Momelotinib (Omjjara)

GlaxoSmithKline GmbH & Co. KG

Anhang 4-I zu Modul 4A

Behandlung von krankheitsbedingter Splenomegalie oder Symptomen bei erwachsenen Patienten mit moderater bis schwerer Anämie, die an primärer Myelofibrose, Post-Polycythaemia Vera-Myelofibrose oder Post-Essentieller Thrombozythämie-Myelofibrose erkrankt sind, und die nicht mit einem Januskinase (JAK)-Inhibitor vorbehandelt sind oder die mit Ruxolitinib behandelt wurden

Stand: 31.10.2025

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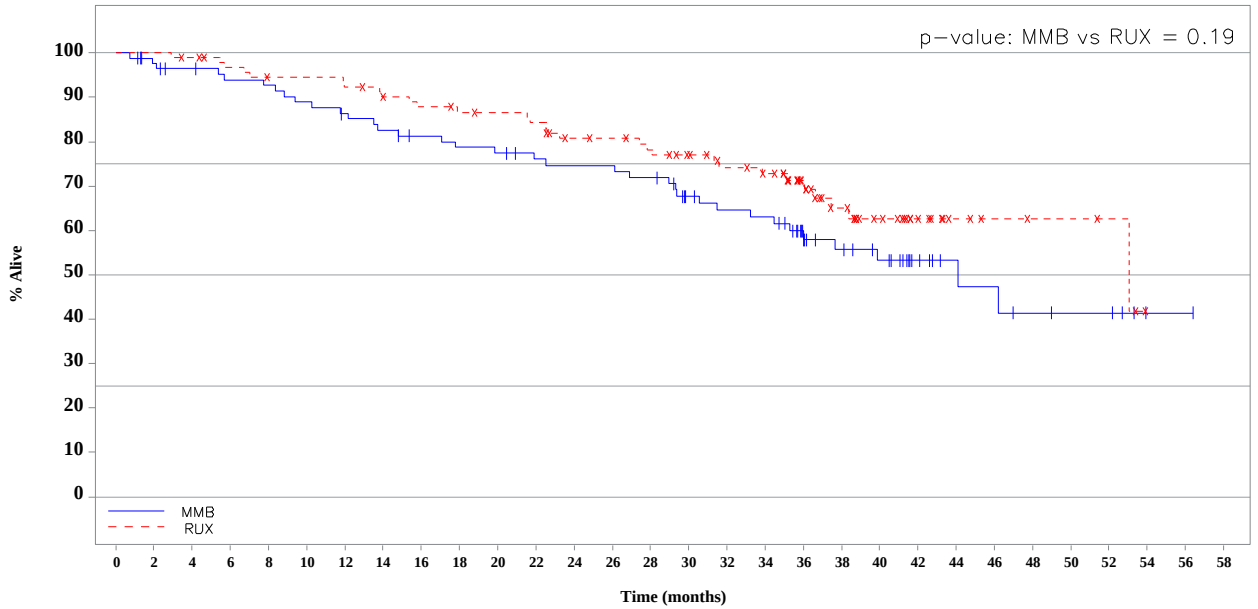
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1 SIMPLIFY-1

1.1 Gesamtüberleben

Figure 3.001: Kaplan-Meier Plot of Overall Survival
Overall (Double-blind + Open-label) Treatment Phase
ITT-Anemic Analysis Set



N at Risk (Events)

MMB	86 (0)	81 (2)	78 (3)	75 (5)	74 (6)	71 (9)	68 (11)	65 (14)	62 (15)	60 (17)	59 (18)	56 (19)	55 (20)	55 (20)	53 (22)	45 (25)	42 (27)	41 (28)	31 (30)	25 (32)	21 (33)	13 (33)	9 (33)	8 (34)	6 (35)	5 (35)	5 (35)	1 (35)	1 (35)	0 (35)
RUX	94 (0)	94 (0)	92 (1)	88 (3)	85 (5)	85 (5)	83 (7)	79 (9)	77 (11)	75 (12)	74 (12)	72 (14)	66 (17)	65 (17)	62 (19)	58 (20)	53 (22)	50 (23)	38 (24)	28 (27)	20 (28)	13 (28)	7 (28)	5 (28)	4 (28)	4 (28)	3 (28)	0 (29)	0 (29)	0 (29)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L).

Data Extracted: CRF data: 01JUL2019
Source: g-os.sas V.03.05 Output file: g-os-comb.pdf 29AUG2023:15:21

Table 2.5501: Overall Survival Analysis
Double-blind Phase and the Overall (Double-blind + Open-label) Treatment Phase
ITT-Anemic Analysis Set

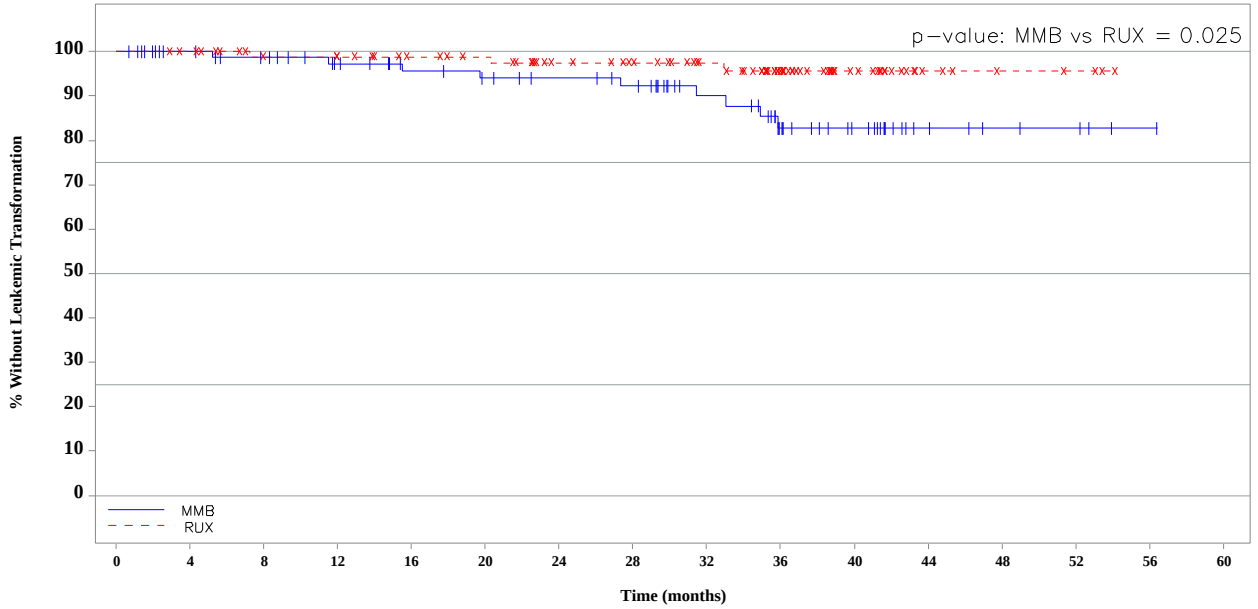
	Overall Treatment Phase		Double-blind Phase	
	MMB (N=86)	RUX (N=94)	MMB (N=86)	RUX (N=94)
Subjects with Event				
Death, n(%)	35 (40.7%)	29 (30.9%)	5 (5.8%)	1 (1.1%)
Subjects Died in DB Phase	5 (14.3%)	1 (3.4%)	5 (100.0%)	1 (100.0%)
Subjects Died in OL Phase	10 (28.6%)	9 (31.0%)	0	0
Subjects Died in follow up	20 (57.1%)	19 (65.5%)	0	0
Censor				
Subjects Censored, n(%)	51 (59.3%)	65 (69.1%)	81 (94.2%)	93 (98.9%)
Kaplan-Meier Estimate of Overall Survival (Months)				
25-percentile (95% CI)	22.51 (13.54, 31.47)	31.61 (21.68, 37.45)	NE (5.68, NE)	NE (NE, NE)
Median (95% CI)	44.09 (34.46, NE)	53.06 (38.41, NE)	NE (5.68, NE)	NE (NE, NE)
75-percentile (95% CI)	NE (46.19, NE)	NE (53.06, NE)	NE (NE, NE)	NE (NE, NE)
Min, Max	0.72, 56.41	2.92, 53.95	0.72, 6.54	2.92, 6.54
Stratified Log-Rank Test p-value	0.19		0.080	
Adjusted Hazard Ratio (95% CI)	1.42 (0.86, 2.35)		6.04 (0.69, 53.18)	
Unstratified Log-Rank Test p-value	0.15		0.050	
Unadjusted Hazard Ratio (95% CI)	1.43 (0.87, 2.34)		6.54 (0.76, 56.36)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Death in the DB phase is death occurring on or after the 1st DB dose up to the earliest of the last DB dose + 30 days, or the 1st OL dose -1 day.
Death in the OL phase is death occurring on or after 1st OL dose up to the last OL MMB dose + 30 days.
Death in the follow-up phase is death occurring after 30 days of the last dose in DB or OL phase, whichever the latest.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019

1.2 Leukämische Transformation

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Figure 2.3.301: Kaplan-Meier Plot of Time to Leukemic Transformation
Overall (Double-blind + Open-label) Treatment Phase
ITT-Anemic Analysis Set



N at Risk (Events)

MMB	86 (0)	78 (0)	73 (1)	66 (2)	60 (3)	57 (4)	54 (4)	51 (5)	40 (6)	28 (9)	19 (9)	8 (9)	5 (9)	4 (9)	1 (9)	0 (9)
RUX	94 (0)	92 (0)	84 (1)	82 (1)	77 (1)	74 (1)	65 (2)	61 (2)	53 (2)	38 (3)	20 (3)	7 (3)	4 (3)	3 (3)	0 (3)	0 (3)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L).

Data Extracted: CRF data: 01JUL2019
Source: g-tte-lt.sas V.03.05 Output file: g-tte-lt-comb.pdf 30AUG2023:12:22

Table 2.5601: Analysis of Time to Leukemic Transformation
Double-blind Phase and the Overall (Double-blind + Open-label) Treatment Phase
ITT-Anemic Analysis Set

	Overall Treatment Phase		Double-blind Phase	
	MMB (N=86)	RUX (N=94)	MMB (N=86)	RUX (N=94)
Subjects with Event				
Leukemic Transformation, n(%)	9 (10.5%)	3 (3.2%)	1 (1.2%)	0
Censor				
Subjects Censored, n(%)	77 (89.5%)	91 (96.8%)	85 (98.8%)	94 (100.0%)
Kaplan-Meier Estimate of Time to Leukemic Transformation (Months)				
25-percentile (95% CI)	NE (34.92, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Min, Max	0.72, 56.41	2.92, 54.11	0.72, 6.54	2.92, 6.54
Stratified Log-Rank Test p-value	0.025		0.14	
Adjusted Hazard Ratio (95% CI)	4.20 (1.12, 15.74)		>999.99 (0.00, NE)	
Unstratified Log-Rank Test p-value	0.033		0.26	
Unadjusted Hazard Ratio (95% CI)	3.77 (1.02, 13.92)		>999.99 (0.00, NE)	

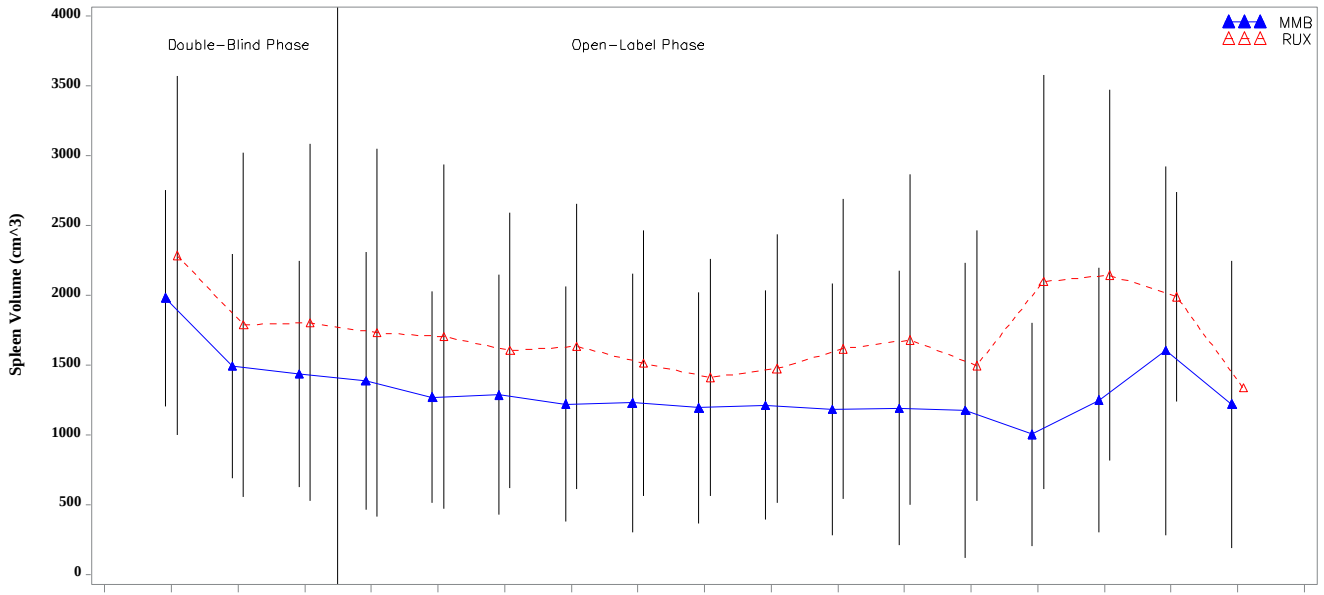
ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-tte-lt.sas V.03.05 Output file: t-tte-lt.pdf 24AUG2023:11:03

1.3 Milzansprechen

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Figure 2.0501: Mean (+/- StD) Plots of Spleen Volume by MRI or CT, Change, and % Change from Baseline (including Baseline)
Combination of Double-Blind Phase and Open-Label Phase
ITT-Anemic Analysis Set

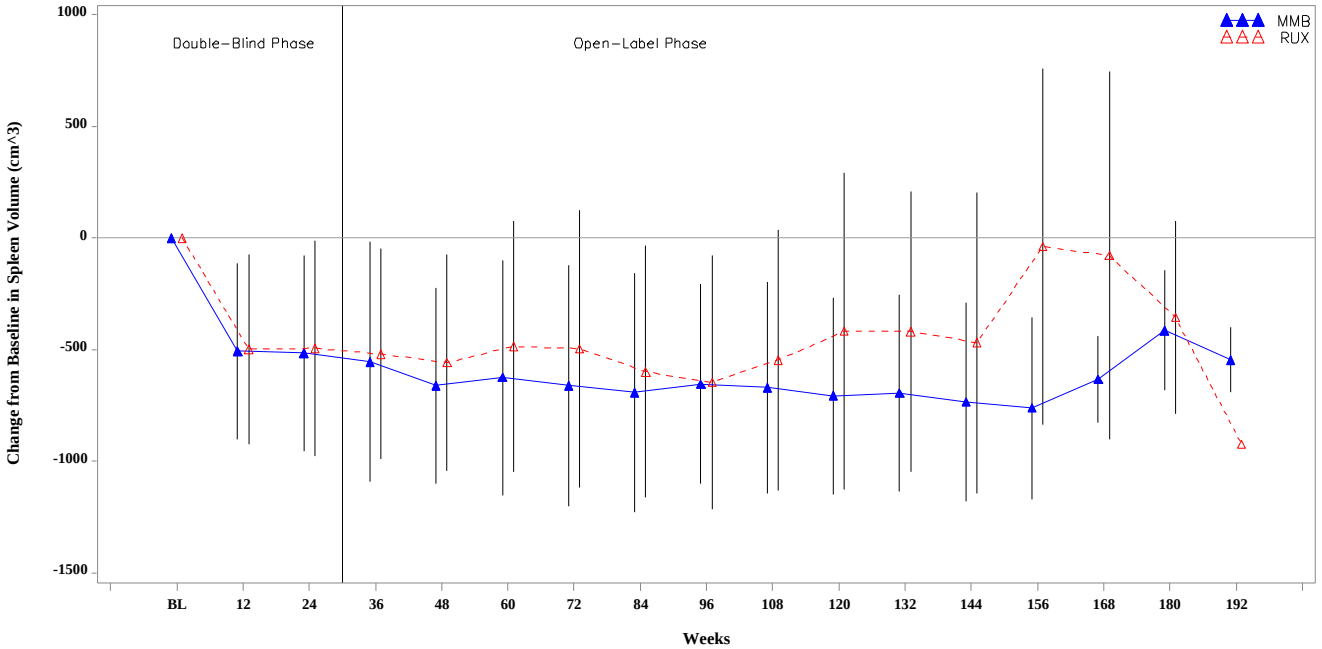


	BL	12	24	36	48	60	72	84	96	108	120	132	144	156	168	180	192
MMB (n)	86	75	70	58	54	46	41	36	31	25	23	19	18	15	10	6	5
RUX (n)	94	89	86	71	67	57	49	45	38	29	30	27	23	16	9	3	1

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Baseline is the last assessment prior to or on the date of 1st dose in the DB phase.
MRI = Magnetic Resonance Imaging
CT = Computerized Tomography

Data Extracted: CRF data: 01JUL2019
Source: g-adhoc-line-comb.sas V.03.05 Output file: adhoc-g-spv-line-pchg-db-ol.pdf 30AUG2023:12:27

Figure 2.0501: Mean (+/- StD) Plots of Spleen Volume by MRI or CT, Change, and % Change from Baseline (including Baseline)
Combination of Double-Blind Phase and Open-Label Phase
ITT-Anemic Analysis Set

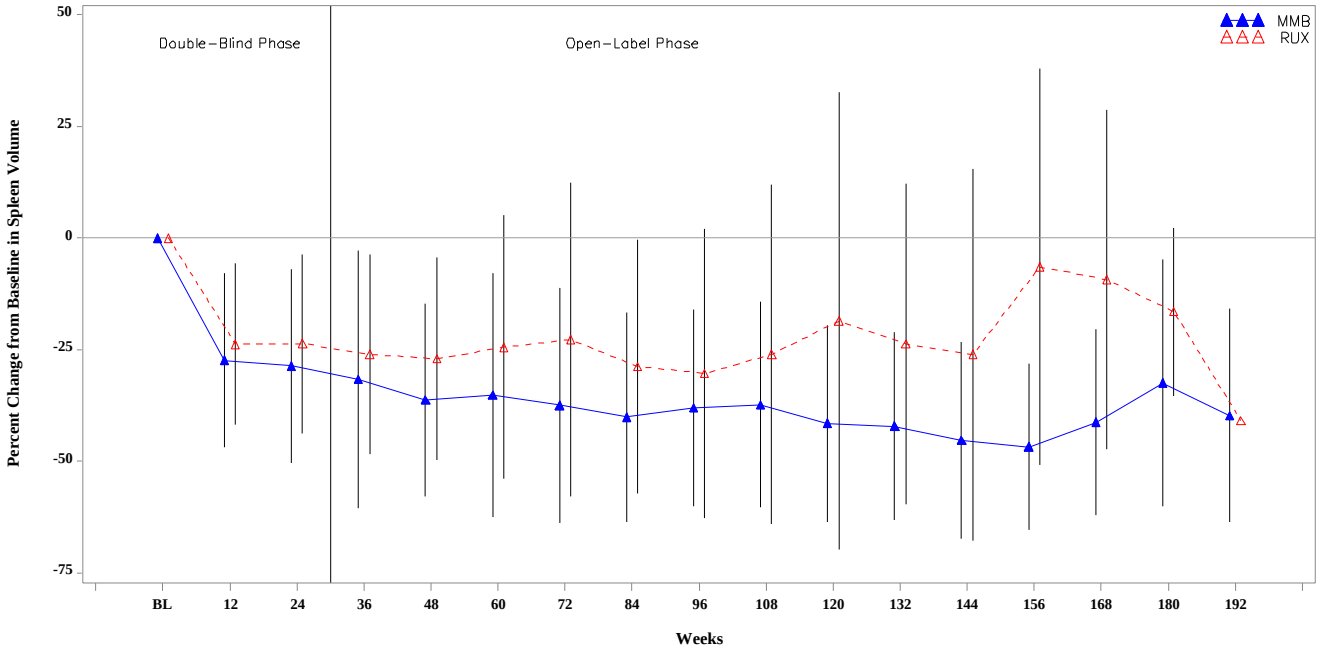


	BL	12	24	36	48	60	72	84	96	108	120	132	144	156	168	180	192
MMB (n)	86	75	70	58	54	46	41	36	31	25	23	19	18	15	10	6	5
RUX (n)	94	89	86	71	67	57	49	45	38	29	30	27	23	16	9	3	1

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Baseline is the last assessment prior to or on the date of 1st dose in the DB phase.
MRI = Magnetic Resonance Imaging
CT = Computerized Tomography

Data Extracted: CRF data: 01JUL2019
Source: g-adhoc-line-comb.sas V.03.05 Output file: adhoc-g-spv-line-pchg-db-ol.pdf 30AUG2023:12:27

Figure 2.0501: Mean (+/- StD) Plots of Spleen Volume by MRI or CT, Change, and % Change from Baseline (including Baseline)
Combination of Double-Blind Phase and Open-Label Phase
ITT-Anemic Analysis Set

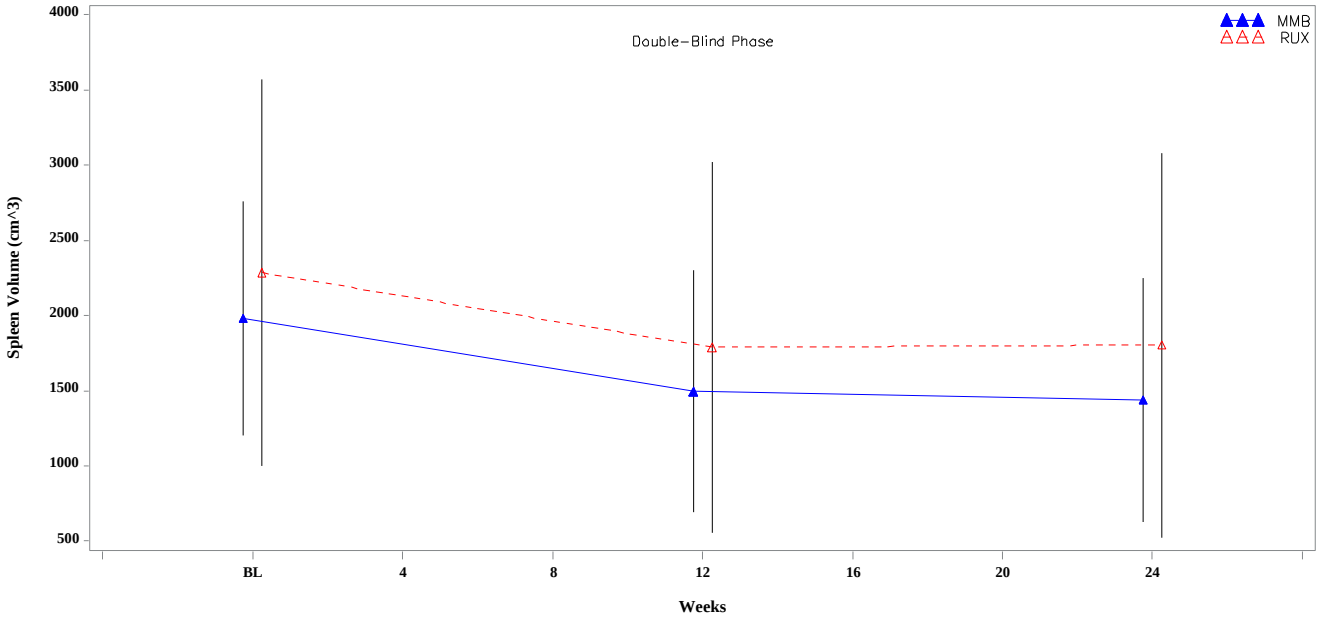


MMB (n)	86	75	70	58	54	46	41	36	31	25	23	19	18	15	10	6	5
RUX (n)	94	89	86	71	67	57	49	45	38	29	30	27	23	16	9	3	1

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Baseline is the last assessment prior to or on the date of 1st dose in the DB phase.
MRI = Magnetic Resonance Imaging
CT = Computerized Tomography

Data Extracted: CRF data: 01JUL2019
Source: g-adhoc-line-comb.sas V.03.05 Output file: adhoc-g-spv-line-pchg-db-ol.pdf 30AUG2023:12:27

Figure 2.0401: Mean (+/- StD) Plots of Spleen Volume by MRI or CT, Change, and % Change from Baseline (including Baseline)
Double-Blind Phase
ITT-Anemic Analysis Set

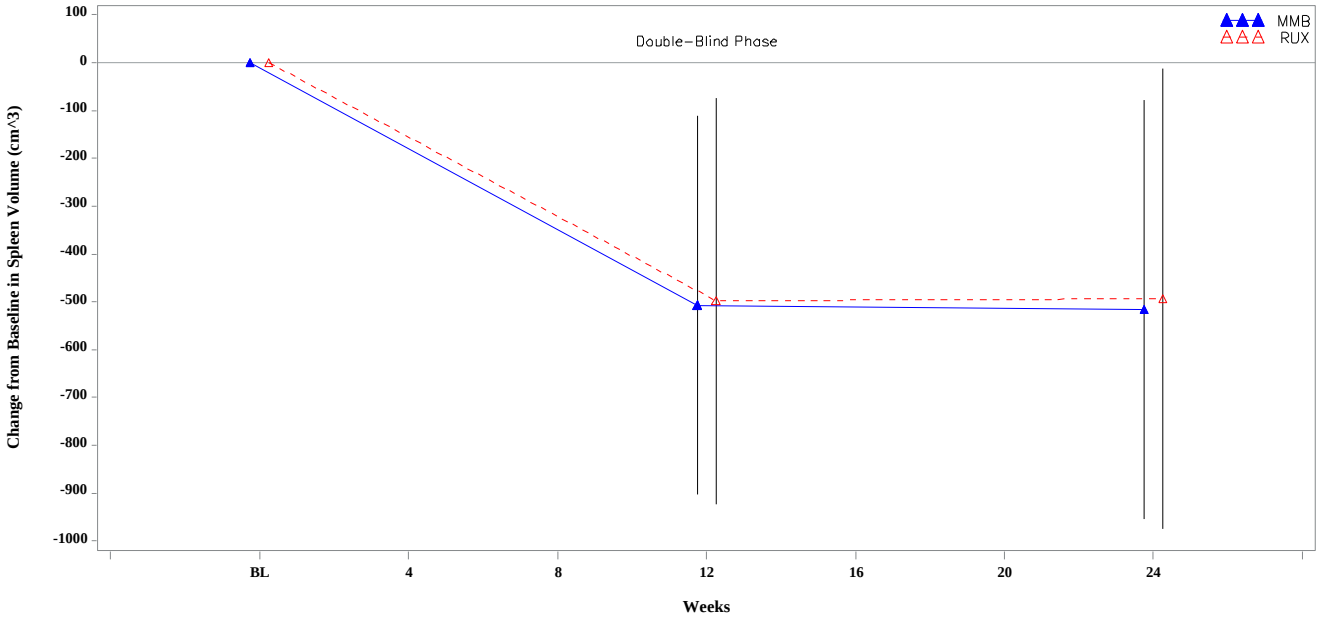


MMB (n)	86	75	70
RUX (n)	94	89	86

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MRI = Magnetic Resonance Imaging
CT = Computerized Tomography

Data Extracted: CRF data: 01JUL2019
Source: g-adhoc-line-comb.sas V.03.05 Output file: adhoc-g-spv-line-pchg-db.pdf 30AUG2023:12:27

Figure 2.0401: Mean (+/- StD) Plots of Spleen Volume by MRI or CT, Change, and % Change from Baseline (including Baseline)
Double-Blind Phase
ITT-Anemic Analysis Set

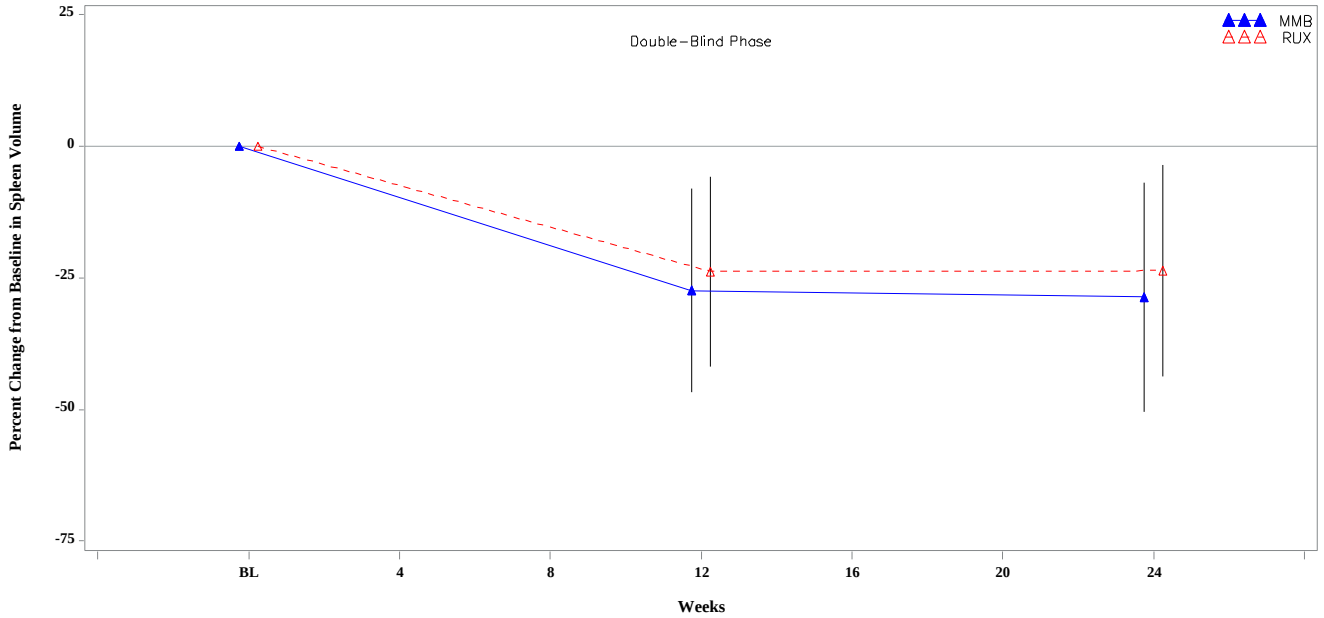


MMB (n)	86	75	70
RUX (n)	94	89	86

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MRI = Magnetic Resonance Imaging
CT = Computerized Tomography

Data Extracted: CRF data: 01JUL2019
Source: g-adhoc-line-comb.sas V.03.05 Output file: adhoc-g-spv-line-pchg-db.pdf 30AUG2023:12:27

Figure 2.0401: Mean (+/- StD) Plots of Spleen Volume by MRI or CT, Change, and % Change from Baseline (including Baseline)
Double-Blind Phase
ITT-Anemic Analysis Set

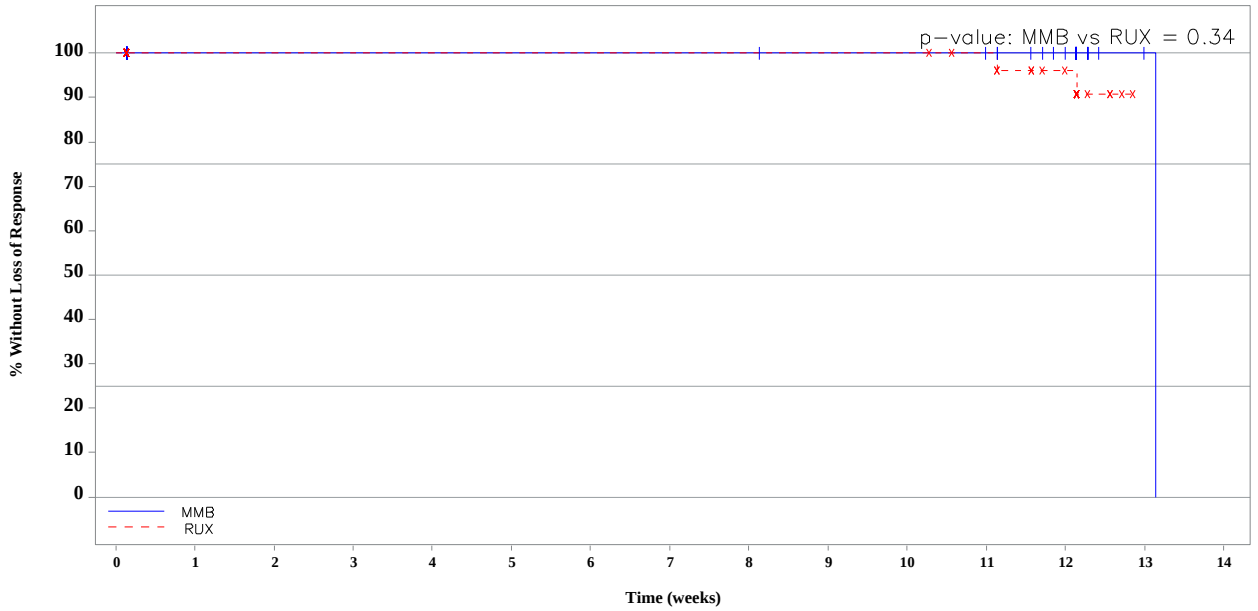


MMB (n)	86	75	70
RUX (n)	94	89	86

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MRI = Magnetic Resonance Imaging
CT = Computerized Tomography

Data Extracted: CRF data: 01JUL2019
Source: g-adhoc-line-comb.sas V.03.05 Output file: adhoc-g-spv-line-pchg-db.pdf 30AUG2023:12:27

Figure 2.0602: Kaplan-Meier Plot of Duration of MRI/CT Splenic Response
Double-blind Phase
ITT-Anemic Analysis Set



N at Risk (Events)

MMB	86 (0)	26 (0)	26 (0)	26 (0)	26 (0)	26 (0)	26 (0)	26 (0)	26 (0)	25 (0)	25 (0)	25 (0)	19 (0)	3 (0)	0 (2)
RUX	94 (0)	27 (0)	27 (0)	27 (0)	27 (0)	27 (0)	27 (0)	27 (0)	27 (0)	27 (0)	27 (0)	25 (0)	19 (1)	0 (2)	0 (2)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L).

Data Extracted: CRF data: 01JUL2019
Source: g-dur-sr.sas V.03.05 Output file: g-dur-sr.pdf 29AUG2023:15:16

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Table 2.0401: Analysis of Spleen Volume, Change and % Change from Baseline at Weeks 12 and 24

Double-Blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Spleen Volume (cm^3) at Baseline		
n	86	94
Mean (SD)	1981.4 (776.14)	2285.2 (1286.90)
Median	1788.1	1958.5
Q1, Q3	1429.9, 2532.6	1367.7, 2831.1
Min, Max	352.0, 4026.8	685.7, 9022.0
Spleen Volume (cm^3) at Week 12		
n	75	89
Mean (SD)	1493.9 (804.43)	1788.2 (1233.95)
Median	1335.4	1506.4
Q1, Q3	847.1, 2008.6	904.9, 2275.0
Min, Max	359.2, 3790.3	376.3, 7907.9
Change in Spleen Volume (cm^3) at Week 12 from Baseline		
n	75	89
Mean (SD)	-507.1 (396.19)	-497.8 (424.46)
Median	-481.0	-472.8
Q1, Q3	-832.0, -273.1	-725.3, -191.3
Min, Max	-1366.5, 617.8	-1536.6, 348.6

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.

[1] Number of subjects with analysable data for one or more time points.

[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.0401: Analysis of Spleen Volume, Change and % Change from Baseline at Weeks 12 and 24
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 12			
n [1]	76	91	
n [2]	75	89	
MMRM: Least Squares Mean [SE] (95% CI)	-491.96 [49.48] (-589.68, -394.24)	-438.04 [46.99] (-530.84, -345.24)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-53.92 [62.30] (-176.96, 69.12)		
MMRM: P-value	0.39		
Corrected Hedges' g (95% CI)	-0.123 (-0.430, 0.185)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.55		
Percent Change in Spleen Volume (cm^3) at Week 12 from Baseline			
n	75	89	
Mean (SD)	-27.4 (19.42)	-23.8 (18.07)	
Median	-27.6	-24.1	
Q1, Q3	-41.8, -13.0	-38.7, -12.2	
Min, Max	-59.2, 24.9	-61.5, 23.9	
Difference in Percent Change from Baseline at Week 12			
n [1]	76	91	
n [2]	75	89	
MMRM: Least Squares Mean [SE] (95% CI)	-26.03 [2.31] (-30.59, -21.47)	-22.49 [2.19] (-26.82, -18.17)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-3.54 [2.91] (-9.28, 2.21)		
MMRM: P-value	0.23		
Corrected Hedges' g (95% CI)	-0.173 (-0.481, 0.135)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.14		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.0401: Analysis of Spleen Volume, Change and % Change from Baseline at Weeks 12 and 24
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Spleen Volume (cm^3) at Week 24		
n	70	86
Mean (SD)	1437.0 (811.94)	1804.1 (1279.12)
Median	1275.6	1531.8
Q1, Q3	817.2, 1945.0	949.1, 2244.2
Min, Max	222.9, 3851.9	335.6, 8287.8
Change in Spleen Volume (cm^3) at Week 24 from Baseline		
n	70	86
Mean (SD)	-516.0 (437.00)	-493.5 (481.34)
Median	-503.4	-425.3
Q1, Q3	-743.9, -257.6	-750.1, -131.4
Min, Max	-1748.5, 671.1	-1682.6, 787.8
Difference in Change from Baseline at Week 24		
n [1]	76	91
n [2]	70	86
MMRM: Least Squares Mean [SE] (95% CI)	-474.98 [55.94] (-585.45, -364.51)	-415.18 [52.52] (-518.92, -311.45)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-59.80 [71.49] (-200.99, 81.40)	
MMRM: P-value	0.40	
Corrected Hedges' g (95% CI)	-0.124 (-0.440, 0.191)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.36	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.0401: Analysis of Spleen Volume, Change and % Change from Baseline at Weeks 12 and 24
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Spleen Volume (cm^3) at Week 24 from Baseline			
n	70	86	
Mean (SD)	-28.6 (21.74)	-23.6 (20.05)	
Median	-29.2	-22.5	
Q1, Q3	-43.9, -14.8	-40.3, -9.4	
Min, Max	-67.7, 26.2	-64.2, 32.2	
Difference in Percent Change from Baseline at Week 24			
n [1]	76	91	
n [2]	70	86	
MMRM: Least Squares Mean [SE] (95% CI)	-25.55 [2.55] (-30.60, -20.51)		-21.81 [2.40] (-26.55, -17.06)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-3.75 [3.26] (-10.18, 2.68)		
MMRM: P-value	0.25		
Corrected Hedges' g (95% CI)	-0.171 (-0.487, 0.146)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.090		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-tss-spleen.sas V.03.05 Output file: t-chg-spv-db-gba.pdf 29AUG2023: 9:33

Table 2.0402: Analysis of Spleen Volume and % Change from Baseline
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open Label Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=64)	Switch (RUX -> MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Spleen Volume at Baseline(cm^3)					
N	64	84	148	86	170
Mean (SD)	1975.2 (807.38)	1735.9 (1184.88)	1839.4 (1042.22)	1981.4 (776.14)	1860.1 (1003.81)
Median	1788.1	1488.9	1635.0	1788.1	1666.3
Q1, Q3	1406.1, 2572.3	950.5, 2110.8	1091.1, 2334.0	1429.9, 2532.6	1147.1, 2474.1
Min, Max	352.0, 4026.8	335.6, 8287.8	335.6, 8287.8	352.0, 4026.8	335.6, 8287.8
Minimum SPV in the Post-Baseline Treatment Period					
N	60	79	139	76	155
Mean (SD)	1218.7 (855.65)	1660.4 (1255.79)	1469.7 (1119.18)	1294.3 (811.62)	1480.9 (1073.91)
Median	996.8	1342.6	1202.2	1171.9	1213.0
Q1, Q3	556.9, 1489.5	892.5, 2112.4	726.1, 1924.1	653.9, 1769.7	801.2, 1945.0
Min, Max	184.4, 4603.2	221.1, 7481.8	184.4, 7481.8	184.4, 3790.3	184.4, 7481.8
Percent of Minimum SPV Change from Baseline in the Post-Baseline Treatment Period					
N	60	79	139	76	155
Mean (SD)	-39.9 (28.82)	-7.0 (27.39)	-21.2 (32.35)	-37.8 (23.57)	-22.1 (29.82)
Median	-42.3	-7.1	-23.9	-36.0	-23.7
Q1, Q3	-59.9, -30.3	-27.1, 11.3	-46.1, -0.1	-58.2, -22.8	-44.0, -1.2
Min, Max	-83.2, 91.5	-73.6, 69.0	-83.2, 91.5	-83.2, 24.9	-83.2, 69.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (RUX->MMB) group, the baseline is the last assessment prior to or on the date of the 1st MMB dose in the OL phase.
For Continuing (MMB->MMB), the baseline is the last assessment prior to or on the date of randomization.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-spv-ol.sas V.03.05 Output file: t-chg-spv-ol.pdf 29AUG2023: 8:56

Table 2.0402: Analysis of Spleen Volume and % Change from Baseline
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open Label Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=64)	Switch (RUX -> MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Maximum SPV in the Post-Baseline Treatment Period					
N	60	79	139	76	155
Mean (SD)	1727.4 (1066.06)	2177.0 (1410.56)	1983.0 (1288.58)	1826.1 (985.28)	2005.0 (1229.44)
Median	1475.2	1821.9	1620.1	1595.4	1700.8
Q1, Q3	944.0, 2329.9	1242.3, 2845.2	1149.0, 2668.9	1101.0, 2396.8	1152.8, 2668.9
Min, Max	294.6, 4603.2	311.1, 8554.1	294.6, 8554.1	359.2, 4603.2	311.1, 8554.1
Percent of Maximum SPV Change from Baseline in the Post-Baseline Treatment Period					
N	60	79	139	76	155
Mean (SD)	-13.2 (34.87)	29.8 (49.87)	11.2 (48.80)	-9.5 (30.16)	10.5 (45.72)
Median	-18.4	22.5	8.0	-14.1	3.2
Q1, Q3	-37.4, 0.8	3.2, 45.7	-18.2, 30.8	-29.2, 2.3	-17.5, 27.3
Min, Max	-72.6, 91.5	-59.3, 296.6	-72.6, 296.6	-59.2, 91.5	-59.3, 296.6
SPV at Week 24 in Open Label Treatment Phase					
N	54	67	121		
Mean (SD)	1269.7 (758.92)	1704.4 (1230.73)	1510.4 (1065.14)		
Median	1122.4	1372.8	1246.9		
Q1, Q3	612.6, 1692.1	981.3, 2227.9	803.3, 1983.5		
Min, Max	294.6, 3423.7	276.4, 7481.8	276.4, 7481.8		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (RUX->MMB) group, the baseline is the last assessment prior to or on the date of the 1st MMB dose in the OL phase.
For Continuing (MMB->MMB), the baseline is the last assessment prior to or on the date of randomization.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-spv-ol.sas V.03.05 Output file: t-chg-spv-ol.pdf 29AUG2023: 8:56

Table 2.0402: Analysis of Spleen Volume and % Change from Baseline
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open Label Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=64)	Switch (RUX -> MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Percent of SPV Change from Baseline at Week 24 in Open Label Treatment Phase					
N	54	67	121		
Mean (SD)	-36.3 (21.51)	0.3 (23.44)	-16.0 (28.98)		
Median	-36.2	1.0	-19.2		
Q1, Q3	-54.4, -23.1	-17.9, 16.3	-35.0, 3.0		
Min, Max	-77.8, 38.3	-67.5, 51.5	-77.8, 51.5		
SPV at Week 12 in Open Label Treatment Phase					
N	58	71	129		
Mean (SD)	1388.6 (923.66)	1731.7 (1318.43)	1577.4 (1166.15)		
Median	1169.9	1402.8	1316.2		
Q1, Q3	638.2, 1948.7	967.8, 2237.8	806.7, 2112.4		
Min, Max	224.3, 4603.2	291.5, 8554.1	224.3, 8554.1		
Percent of SPV Change from Baseline at Week 12 in Open Label Treatment Phase					
N	58	71	129		
Mean (SD)	-31.6 (28.75)	2.0 (21.97)	-13.1 (30.25)		
Median	-34.2	1.1	-13.2		
Q1, Q3	-56.1, -20.2	-13.2, 17.4	-32.4, 8.0		
Min, Max	-76.4, 91.5	-59.3, 52.4	-76.4, 91.5		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (RUX->MMB) group, the baseline is the last assessment prior to or on the date of the 1st MMB dose in the OL phase.
For Continuing (MMB->MMB), the baseline is the last assessment prior to or on the date of randomization.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-spv-ol.sas V.03.05 Output file: t-chg-spv-ol.pdf 29AUG2023: 8:56

Table 2.0402: Analysis of Spleen Volume and % Change from Baseline
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open Label Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=64)	Switch (RUX -> MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
SPV at Week 36 in Open Label Treatment Phase					
N	46	57	103		
Mean (SD)	1287.3 (860.54)	1605.7 (986.81)	1463.5 (941.62)		
Median	1034.1	1467.8	1261.8		
Q1, Q3	553.8, 1905.3	966.7, 2127.2	684.2, 2124.0		
Min, Max	283.6, 3900.3	248.4, 5206.2	248.4, 5206.2		
Percent of SPV Change from Baseline at Week 36 in Open Label Treatment Phase					
N	46	57	103		
Mean (SD)	-35.2 (27.33)	4.3 (31.94)	-13.4 (35.75)		
Median	-37.4	3.1	-20.4		
Q1, Q3	-54.4, -23.0	-20.6, 22.5	-39.5, 9.7		
Min, Max	-80.9, 72.8	-73.6, 90.0	-80.9, 90.0		
SPV at Week 48 in Open Label Treatment Phase					
N	41	49	90		
Mean (SD)	1220.5 (841.78)	1634.4 (1022.87)	1445.8 (962.13)		
Median	1073.1	1357.8	1245.4		
Q1, Q3	516.2, 1497.6	1018.4, 2278.4	656.4, 2039.1		
Min, Max	245.8, 4217.3	221.1, 5413.6	221.1, 5413.6		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (RUX->MMB) group, the baseline is the last assessment prior to or on the date of the 1st MMB dose in the OL phase.
For Continuing (MMB->MMB), the baseline is the last assessment prior to or on the date of randomization.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-spv-ol.sas V.03.05 Output file: t-chg-spv-ol.pdf 29AUG2023: 8:56

Table 2.0402: Analysis of Spleen Volume and % Change from Baseline
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open Label Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=64)	Switch (RUX -> MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Percent of SPV Change from Baseline at Week 48 in Open Label Treatment Phase					
N	41	49	90		
Mean (SD)	-37.4 (26.30)	3.4 (34.65)	-15.2 (37.12)		
Median	-39.4	0.3	-21.9		
Q1, Q3	-55.5, -29.1	-20.9, 20.9	-39.9, 7.6		
Min, Max	-83.0, 54.0	-56.6, 115.8	-83.0, 115.8		
SPV at Week 60 in Open Label Treatment Phase					
N	36	45	81		
Mean (SD)	1229.7 (927.32)	1513.4 (952.16)	1387.3 (946.03)		
Median	1047.0	1273.4	1238.4		
Q1, Q3	497.6, 1399.2	862.2, 2129.2	645.2, 1693.7		
Min, Max	184.4, 4410.6	228.5, 4349.9	184.4, 4410.6		
Percent of SPV Change from Baseline at Week 60 in Open Label Treatment Phase					
N	36	45	81		
Mean (SD)	-40.1 (23.45)	-0.5 (30.54)	-18.1 (33.84)		
Median	-45.3	-8.4	-21.1		
Q1, Q3	-56.8, -23.1	-20.4, 12.6	-43.0, -3.9		
Min, Max	-83.2, 41.7	-45.4, 80.1	-83.2, 80.1		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (RUX->MMB) group, the baseline is the last assessment prior to or on the date of the 1st MMB dose in the OL phase.
For Continuing (MMB->MMB), the baseline is the last assessment prior to or on the date of randomization.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-spv-ol.sas V.03.05 Output file: t-chg-spv-ol.pdf 29AUG2023: 8:56

Table 2.0402: Analysis of Spleen Volume and % Change from Baseline
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open Label Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=64)	Switch (RUX -> MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
SPV at Week 72 in Open Label Treatment Phase					
N	31	38	69		
Mean (SD)	1194.6 (826.09)	1411.5 (850.59)	1314.0 (840.57)		
Median	1002.0	1193.5	1163.6		
Q1, Q3	451.1, 1517.5	881.3, 1954.6	729.3, 1724.5		
Min, Max	250.5, 3140.3	268.1, 4592.4	250.5, 4592.4		
Percent of SPV Change from Baseline at Week 72 in Open Label Treatment Phase					
N	31	38	69		
Mean (SD)	-38.0 (22.03)	-2.1 (34.96)	-18.2 (34.68)		
Median	-44.4	-6.9	-19.0		
Q1, Q3	-56.0, -19.0	-23.0, 9.9	-45.9, -1.2		
Min, Max	-82.9, -1.2	-63.9, 123.1	-82.9, 123.1		
SPV at Week 84 in Open Label Treatment Phase					
N	25	29	54		
Mean (SD)	1212.0 (821.02)	1474.5 (961.99)	1353.0 (900.89)		
Median	1071.6	1393.4	1270.8		
Q1, Q3	516.7, 1512.9	999.3, 1881.8	603.4, 1601.3		
Min, Max	281.2, 3341.6	267.9, 4742.2	267.9, 4742.2		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (RUX->MMB) group, the baseline is the last assessment prior to or on the date of the 1st MMB dose in the OL phase.
For Continuing (MMB->MMB), the baseline is the last assessment prior to or on the date of randomization.

Data Extracted: CRF data: 01JUL2019

Table 2.0402: Analysis of Spleen Volume and % Change from Baseline
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open Label Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=64)	Switch (RUX -> MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Percent of SPV Change from Baseline at Week 84 in Open Label Treatment Phase					
N	25	29	54		
Mean (SD)	-37.4 (23.03)	2.7 (40.88)	-15.8 (39.11)		
Median	-44.6	-5.8	-18.2		
Q1, Q3	-53.6, -19.0	-18.8, 22.0	-48.2, -4.6		
Min, Max	-82.3, 12.3	-63.9, 126.3	-82.3, 126.3		
SPV at Week 96 in Open Label Treatment Phase					
N	23	30	53		
Mean (SD)	1184.2 (903.33)	1617.9 (1073.06)	1429.7 (1017.10)		
Median	990.7	1424.4	1201.6		
Q1, Q3	464.6, 1592.6	976.5, 1998.8	512.8, 1821.9		
Min, Max	262.0, 3401.2	291.4, 5189.4	262.0, 5189.4		
Percent of SPV Change from Baseline at Week 96 in Open Label Treatment Phase					
N	23	30	53		
Mean (SD)	-41.5 (22.00)	10.7 (53.06)	-11.9 (49.58)		
Median	-48.0	3.1	-16.7		
Q1, Q3	-57.5, -16.7	-19.5, 26.0	-48.0, 4.3		
Min, Max	-81.0, 2.6	-55.3, 205.1	-81.0, 205.1		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (RUX->MMB) group, the baseline is the last assessment prior to or on the date of the 1st MMB dose in the OL phase.
For Continuing (MMB->MMB), the baseline is the last assessment prior to or on the date of randomization.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-spv-ol.sas V.03.05 Output file: t-chg-spv-ol.pdf 29AUG2023: 8:56

Table 2.0402: Analysis of Spleen Volume and % Change from Baseline
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open Label Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=64)	Switch (RUX -> MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
SPV at Week 108 in Open Label Treatment Phase					
N	19	27	46		
Mean (SD)	1190.9 (983.97)	1681.3 (1184.90)	1478.8 (1121.64)		
Median	746.7	1358.1	1220.7		
Q1, Q3	430.6, 1778.6	815.6, 2307.1	492.0, 2156.0		
Min, Max	234.0, 3611.9	264.4, 5409.2	234.0, 5409.2		
Percent of SPV Change from Baseline at Week 108 in Open Label Treatment Phase					
N	19	27	46		
Mean (SD)	-42.1 (20.95)	5.7 (46.13)	-14.0 (44.40)		
Median	-47.2	-2.4	-15.4		
Q1, Q3	-60.6, -29.7	-15.9, 22.2	-47.2, 9.7		
Min, Max	-81.5, -6.9	-64.4, 166.3	-81.5, 166.3		
SPV at Week 120 in Open Label Treatment Phase					
N	18	23	41		
Mean (SD)	1176.6 (1057.92)	1496.6 (968.20)	1356.1 (1008.50)		
Median	593.5	1225.4	1064.5		
Q1, Q3	443.1, 1563.3	689.6, 2379.4	454.7, 2279.1		
Min, Max	221.2, 3790.8	279.4, 3424.9	221.2, 3790.8		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (RUX->MMB) group, the baseline is the last assessment prior to or on the date of the 1st MMB dose in the OL phase.
For Continuing (MMB->MMB), the baseline is the last assessment prior to or on the date of randomization.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-spv-ol.sas V.03.05 Output file: t-chg-spv-ol.pdf 29AUG2023: 8:56

Table 2.0402: Analysis of Spleen Volume and % Change from Baseline
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open Label Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=64)	Switch (RUX -> MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Percent of SPV Change from Baseline at Week 120 in Open Label Treatment Phase					
N	18	23	41		
Mean (SD)	-45.3 (22.11)	3.7 (60.63)	-17.8 (53.25)		
Median	-52.5	-3.6	-20.7		
Q1, Q3	-61.6, -20.7	-30.9, 16.2	-53.4, -2.5		
Min, Max	-82.4, -5.9	-62.4, 243.4	-82.4, 243.4		
SPV at Week 132 in Open Label Treatment Phase					
N	15	16	31		
Mean (SD)	1004.3 (799.26)	2098.7 (1484.48)	1569.2 (1307.31)		
Median	708.6	1798.9	1199.6		
Q1, Q3	417.1, 1443.9	1034.7, 3096.3	510.8, 2272.3		
Min, Max	234.0, 2773.5	415.0, 6026.9	234.0, 6026.9		
Percent of SPV Change from Baseline at Week 132 in Open Label Treatment Phase					
N	15	16	31		
Mean (SD)	-46.7 (18.63)	31.6 (74.24)	-6.3 (67.08)		
Median	-50.4	15.9	-17.9		
Q1, Q3	-61.4, -33.5	0.7, 33.3	-50.4, 17.8		
Min, Max	-74.8, -15.1	-31.6, 296.6	-74.8, 296.6		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (RUX->MMB) group, the baseline is the last assessment prior to or on the date of the 1st MMB dose in the OL phase.
For Continuing (MMB->MMB), the baseline is the last assessment prior to or on the date of randomization.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-spv-ol.sas V.03.05 Output file: t-chg-spv-ol.pdf 29AUG2023: 8:56

Table 2.0402: Analysis of Spleen Volume and % Change from Baseline
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open Label Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=64)	Switch (RUX -> MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
SPV at Week 144 in Open Label Treatment Phase					
N	10	9	19		
Mean (SD)	1248.7 (948.11)	2145.3 (1327.49)	1673.4 (1201.77)		
Median	1038.0	1770.6	1484.5		
Q1, Q3	393.6, 1553.6	1432.3, 2940.3	581.0, 2800.0		
Min, Max	375.7, 2829.9	414.0, 4447.7	375.7, 4447.7		
Percent of SPV Change from Baseline at Week 144 in Open Label Treatment Phase					
N	10	9	19		
Mean (SD)	-41.2 (20.90)	18.7 (32.01)	-12.8 (40.25)		
Median	-42.6	14.2	-14.6		
Q1, Q3	-63.2, -22.6	8.7, 23.6	-49.4, 14.2		
Min, Max	-66.1, -13.4	-31.8, 79.8	-66.1, 79.8		
SPV at Week 156 in Open Label Treatment Phase					
N	6	3	9		
Mean (SD)	1605.2 (1321.78)	1988.4 (750.02)	1733.0 (1126.62)		
Median	1306.2	1671.8	1671.8		
Q1, Q3	359.0, 2977.9	1448.5, 2844.8	777.6, 2844.8		
Min, Max	349.6, 3332.6	1448.5, 2844.8	349.6, 3332.6		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (RUX->MMB) group, the baseline is the last assessment prior to or on the date of the 1st MMB dose in the OL phase.
For Continuing (MMB->MMB), the baseline is the last assessment prior to or on the date of randomization.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-spv-ol.sas V.03.05 Output file: t-chg-spv-ol.pdf 29AUG2023: 8:56

Table 2.0402: Analysis of Spleen Volume and % Change from Baseline
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open Label Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=64)	Switch (RUX -> MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Percent of SPV Change from Baseline at Week 156 in Open Label Treatment Phase					
N	6	3	9		
Mean (SD)	-32.4 (27.60)	3.0 (9.30)	-20.6 (28.47)		
Median	-30.9	2.6	-8.9		
Q1, Q3	-58.4, -8.9	-6.2, 12.4	-41.1, 1.6		
Min, Max	-67.1, 1.6	-6.2, 12.4	-67.1, 12.4		
SPV at Week 168 in Open Label Treatment Phase					
N	5	1	6		
Mean (SD)	1220.8 (1029.53)	1338.3	1240.3 (922.09)		
Median	906.7	1338.3	1122.5		
Q1, Q3	359.6, 1833.4	1338.3, 1338.3	359.6, 1833.4		
Min, Max	304.9, 2699.1	1338.3, 1338.3	304.9, 2699.1		
Percent of SPV Change from Baseline at Week 168 in Open Label Treatment Phase					
N	5	1	6		
Mean (SD)	-39.8 (23.90)	-13.3	-35.3 (23.95)		
Median	-31.3	-13.3	-26.0		
Q1, Q3	-57.2, -20.7	-13.3, -13.3	-57.2, -17.4		
Min, Max	-72.1, -17.4	-13.3, -13.3	-72.1, -13.3		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (RUX->MMB) group, the baseline is the last assessment prior to or on the date of the 1st MMB dose in the OL phase.
For Continuing (MMB->MMB), the baseline is the last assessment prior to or on the date of randomization.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-spv-ol.sas V.03.05 Output file: t-chg-spv-ol.pdf 29AUG2023: 8:56

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Table 2.0503: Analysis of Duration of MRI/CT Splenic Response by Age
Double-blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Subjects with Event					
Loss of spleen response, n(%)	1 (4.2%)	0	1 (1.6%)	2 (3.4%)	
Censor					
Subjects Censored, n(%)	23 (95.8%)	36 (100.0%)	61 (98.4%)	56 (96.6%)	
Non-Responder: Censored at Randomization Date	16 (69.6%)	23 (63.9%)	39 (63.9%)	35 (62.5%)	
No Loss of Response: Censored at Last MRI Spleen Assessment Date in DB phase (including up to 10 days after First Dose Date of OL phase)	7 (30.4%)	13 (36.1%)	22 (36.1%)	21 (37.5%)	
Kaplan-Meier Estimate of Duration of Spleen Response (Weeks)					
25-percentile (95% CI)	13.14 (NE, NE)	NE (NE, NE)	13.14 (NE, NE)	NE (11.14, NE)	
Median (95% CI)	13.14 (NE, NE)	NE (NE, NE)	13.14 (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	13.14 (NE, NE)	NE (NE, NE)	13.14 (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 13.14	0.14, 12.86	0.14, 13.14	0.14, 12.71	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction.
MRI = Magnetic Resonance Imaging. CT = Computerized Tomography.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-sr-sub.sas V.03.05 Output file: t-dur-sr-age.pdf 24AUG2023:12:41

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Table 2.0505: Analysis of Duration of MRI/CT Splenic Response by Region
Double-blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Subjects with Event					
Loss of spleen response, n(%)	1 (1.9%)	0	1 (3.0%)	2 (4.7%)	
Censor					
Subjects Censored, n(%)	52 (98.1%)	51 (100.0%)	32 (97.0%)	41 (95.3%)	
Non-Responder: Censored at Randomization Date	34 (65.4%)	35 (68.6%)	21 (65.6%)	23 (56.1%)	
No Loss of Response: Censored at Last MRI Spleen Assessment Date in DB phase (including up to 10 days after First Dose Date of OL phase)	18 (34.6%)	16 (31.4%)	11 (34.4%)	18 (43.9%)	
Kaplan-Meier Estimate of Duration of Spleen Response (Weeks)					
25-percentile (95% CI)	13.14 (NE, NE)	NE (NE, NE)	13.14 (NE, NE)	NE (11.14, NE)	
Median (95% CI)	13.14 (NE, NE)	NE (NE, NE)	13.14 (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	13.14 (NE, NE)	NE (NE, NE)	13.14 (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 13.14	0.14, 12.71	0.14, 13.14	0.14, 12.86	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction.
MRI = Magnetic Resonance Imaging. CT = Computerized Tomography.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-sr-sub.sas V.03.05 Output file: t-dur-sr-geo.pdf 24AUG2023:12:41

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Table 2.0508: Analysis of Duration of MRI/CT Splenic Response by Baseline Hemoglobin Level
Double-blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Subjects with Event					
Loss of spleen response, n(%)	0	1 (4.8%)	2 (3.4%)	1 (1.4%)	
Censor					
Subjects Censored, n(%)	28 (100.0%)	20 (95.2%)	56 (96.6%)	72 (98.6%)	
Non-Responder: Censored at Randomization Date	20 (71.4%)	13 (65.0%)	35 (62.5%)	45 (62.5%)	
No Loss of Response: Censored at Last MRI Spleen Assessment Date in DB phase (including up to 10 days after First Dose Date of OL phase)	8 (28.6%)	7 (35.0%)	21 (37.5%)	27 (37.5%)	
Kaplan-Meier Estimate of Duration of Spleen Response (Weeks)					
25-percentile (95% CI)	NE (NE, NE)	12.14 (12.14, NE)	13.14 (NE, NE)	NE (11.14, NE)	
Median (95% CI)	NE (NE, NE)	NE (12.14, NE)	13.14 (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (12.14, NE)	13.14 (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 13.00	0.14, 12.86	0.14, 13.14	0.14, 12.71	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction.
MRI = Magnetic Resonance Imaging. CT = Computerized Tomography.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-sr-sub.sas V.03.05 Output file: t-dur-sr-hgb.pdf 24AUG2023:12:41

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Table 2.0507: Analysis of Duration of MRI/CT Splenic Response by Baseline IPSS Two-Level Risk

Double-blind Phase

ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Subjects with Event					
Loss of spleen response, n(%)	0	0	2 (3.4%)	2 (2.9%)	
Censor					
Subjects Censored, n(%)	28 (100.0%)	24 (100.0%)	56 (96.6%)	68 (97.1%)	
Non-Responder: Censored at Randomization Date	19 (67.9%)	15 (62.5%)	36 (64.3%)	43 (63.2%)	
No Loss of Response: Censored at Last MRI Spleen Assessment Date in DB phase (including up to 10 days after First Dose Date of OL phase)	9 (32.1%)	9 (37.5%)	20 (35.7%)	25 (36.8%)	
Kaplan-Meier Estimate of Duration of Spleen Response (Weeks)					
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	13.14 (NE, NE)	NE (11.14, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	13.14 (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	13.14 (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 12.29	0.14, 12.86	0.14, 13.14	0.14, 12.71	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction.
MRI = Magnetic Resonance Imaging. CT = Computerized Tomography.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-sr-sub.sas V.03.05 Output file: t-dur-sr-ipss2.pdf 24AUG2023:12:41

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Table 2.0506: Analysis of Duration of MRI/CT Splenic Response by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Subjects with Event				
Loss of spleen response, n(%)	0	0	0	0
Censor				
Subjects Censored, n(%)	2 (100.0%)	4 (100.0%)	26 (100.0%)	20 (100.0%)
Non-Responder: Censored at Randomization Date	0	2 (50.0%)	19 (73.1%)	13 (65.0%)
No Loss of Response: Censored at Last MRI Spleen Assessment Date in DB phase (including up to 10 days after First Dose Date of OL phase)	2 (100.0%)	2 (50.0%)	7 (26.9%)	7 (35.0%)
Kaplan-Meier Estimate of Duration of Spleen Response (Weeks)				
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Min, Max	12.14, 12.29	0.14, 12.14	0.14, 12.29	0.14, 12.86
Stratified Log-Rank Test p-value	NA		NA	
Adjusted Hazard Ratio (95% CI)	NA		NA	
Unstratified Log-Rank Test p-value	NA		NA	
Unadjusted Hazard Ratio (95% CI)	NA		NA	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction.
MRI = Magnetic Resonance Imaging. CT = Computerized Tomography.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-sr-sub.sas V.03.05 Output file: t-dur-sr-ipss3.pdf 24AUG2023:12:41

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Table 2.0506: Analysis of Duration of MRI/CT Splenic Response by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=58)	High Risk RUX (N=70)	p-value
Subjects with Event			
Loss of spleen response, n(%)	2 (3.4%)	2 (2.9%)	
Censor			
Subjects Censored, n(%)	56 (96.6%)	68 (97.1%)	
Non-Responder: Censored at Randomization Date	36 (64.3%)	43 (63.2%)	
No Loss of Response: Censored at Last MRI Spleen Assessment Date in DB phase (including up to 10 days after First Dose Date of OL phase)	20 (35.7%)	25 (36.8%)	
Kaplan-Meier Estimate of Duration of Spleen Response (Weeks)			
25-percentile (95% CI)	13.14 (NE, NE)	NE (11.14, NE)	
Median (95% CI)	13.14 (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	13.14 (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 13.14	0.14, 12.71	
Stratified Log-Rank Test p-value	NA		
Adjusted Hazard Ratio (95% CI)	NA		
Unstratified Log-Rank Test p-value	NA		
Unadjusted Hazard Ratio (95% CI)	NA		
P-value for interaction test			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction.
MRI = Magnetic Resonance Imaging. CT = Computerized Tomography.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-sr-sub.sas V.03.05 Output file: t-dur-sr-ipss3.pdf 24AUG2023:12:41

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Table 2.0509: Analysis of Duration of MRI/CT Splenic Response by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=16)	RUX (N=28)	MMB (N=11)	RUX (N=12)
Subjects with Event				
Loss of spleen response, n(%)	0	1 (3.6%)	0	0
Censor				
Subjects Censored, n(%)	16 (100.0%)	27 (96.4%)	11 (100.0%)	12 (100.0%)
Non-Responder: Censored at Randomization Date	14 (87.5%)	16 (59.3%)	7 (63.6%)	6 (50.0%)
No Loss of Response: Censored at Last MRI Spleen Assessment Date in DB phase (including up to 10 days after First Dose Date of OL phase)	2 (12.5%)	11 (40.7%)	4 (36.4%)	6 (50.0%)
Kaplan-Meier Estimate of Duration of Spleen Response (Weeks)				
25-percentile (95% CI)	NE (NE, NE)	NE (12.14, NE)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (12.14, NE)	NE (NE, NE)	NE (NE, NE)
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Min, Max	0.14, 12.14	0.14, 12.86	0.14, 12.14	0.14, 12.71
Stratified Log-Rank Test p-value	NA		NA	
Adjusted Hazard Ratio (95% CI)	NA		NA	
Unstratified Log-Rank Test p-value	NA		NA	
Unadjusted Hazard Ratio (95% CI)	NA		NA	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction.
MRI = Magnetic Resonance Imaging. CT = Computerized Tomography.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-sr-sub.sas V.03.05 Output file: t-dur-sr-mf.pdf 24AUG2023:12:41

Table 2.0509: Analysis of Duration of MRI/CT Splenic Response by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	Primary Myelofibrosis MMB (N=59)	Primary Myelofibrosis RUX (N=54)	p-value
Subjects with Event			
Loss of spleen response, n(%)	2 (3.4%)	1 (1.9%)	
Censor			
Subjects Censored, n(%)	57 (96.6%)	53 (98.1%)	
Non-Responder: Censored at Randomization Date	34 (59.6%)	36 (67.9%)	
No Loss of Response: Censored at Last MRI Spleen Assessment Date in DB phase (including up to 10 days after First Dose Date of OL phase)	23 (40.4%)	17 (32.1%)	
Kaplan-Meier Estimate of Duration of Spleen Response (Weeks)			
25-percentile (95% CI)	13.14 (NE, NE)	NE (11.14, NE)	
Median (95% CI)	13.14 (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	13.14 (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 13.14	0.14, 12.57	
Stratified Log-Rank Test p-value	NA		
Adjusted Hazard Ratio (95% CI)	NA		
Unstratified Log-Rank Test p-value	NA		
Unadjusted Hazard Ratio (95% CI)	NA		
P-value for interaction test			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction.
MRI = Magnetic Resonance Imaging. CT = Computerized Tomography.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-sr-sub.sas V.03.05 Output file: t-dur-sr-mf.pdf 24AUG2023:12:41

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Table 2.0504: Analysis of Duration of MRI/CT Splenic Response by Gender
Double-blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Subjects with Event					
Loss of spleen response, n(%)	1 (2.0%)	1 (1.8%)	1 (2.8%)	1 (2.6%)	
Censor					
Subjects Censored, n(%)	49 (98.0%)	55 (98.2%)	35 (97.2%)	37 (97.4%)	
Non-Responder: Censored at Randomization Date	33 (67.3%)	39 (70.9%)	22 (62.9%)	19 (51.4%)	
No Loss of Response: Censored at Last MRI Spleen Assessment Date in DB phase (including up to 10 days after First Dose Date of OL phase)	16 (32.7%)	16 (29.1%)	13 (37.1%)	18 (48.6%)	
Kaplan-Meier Estimate of Duration of Spleen Response (Weeks)					
25-percentile (95% CI)	13.14 (NE, NE)	NE (11.14, NE)	13.14 (NE, NE)	NE (12.14, NE)	
Median (95% CI)	13.14 (NE, NE)	NE (11.14, NE)	13.14 (NE, NE)	NE (12.14, NE)	
75-percentile (95% CI)	13.14 (NE, NE)	NE (NE, NE)	13.14 (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 13.14	0.14, 12.86	0.14, 13.14	0.14, 12.57	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction.
MRI = Magnetic Resonance Imaging. CT = Computerized Tomography.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-sr-sub.sas V.03.05 Output file: t-dur-sr-sex.pdf 24AUG2023:12:41

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Table 2.0511: Analysis of Duration of MRI/CT Splenic Response by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Subjects with Event					
Loss of spleen response, n(%)	1 (2.1%)	1 (2.3%)	1 (2.6%)	1 (2.0%)	
Censor					
Subjects Censored, n(%)	46 (97.9%)	42 (97.7%)	38 (97.4%)	50 (98.0%)	
Non-Responder: Censored at Randomization Date	26 (56.5%)	22 (52.4%)	29 (76.3%)	36 (72.0%)	
No Loss of Response: Censored at Last MRI Spleen Assessment Date in DB phase (including up to 10 days after First Dose Date of OL phase)	20 (43.5%)	20 (47.6%)	9 (23.7%)	14 (28.0%)	
Kaplan-Meier Estimate of Duration of Spleen Response (Weeks)					
25-percentile (95% CI)	13.14 (NE, NE)	NE (11.14, NE)	13.14 (NE, NE)	NE (12.14, NE)	
Median (95% CI)	13.14 (NE, NE)	NE (NE, NE)	13.14 (NE, NE)	NE (12.14, NE)	
75-percentile (95% CI)	13.14 (NE, NE)	NE (NE, NE)	13.14 (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 13.14	0.14, 12.57	0.14, 13.14	0.14, 12.86	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction.
MRI = Magnetic Resonance Imaging. CT = Computerized Tomography.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-sr-sub.sas V.03.05 Output file: t-dur-sr-svb.pdf 24AUG2023:12:41

GSK Oncology
Study GS-US-352-0101

Table 2.0510: Analysis of Duration of MRI/CT Splenic Response by Baseline TSS
Double-blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Subjects with Event					
Loss of spleen response, n(%)	1 (2.3%)	2 (3.6%)	1 (2.4%)	0	
Censor					
Subjects Censored, n(%)	43 (97.7%)	53 (96.4%)	40 (97.6%)	38 (100.0%)	
Non-Responder: Censored at Randomization Date	25 (58.1%)	35 (66.0%)	30 (75.0%)	22 (57.9%)	
No Loss of Response: Censored at Last MRI Spleen Assessment Date in DB phase (including up to 10 days after First Dose Date of OL phase)	18 (41.9%)	18 (34.0%)	10 (25.0%)	16 (42.1%)	
Kaplan-Meier Estimate of Duration of Spleen Response (Weeks)					
25-percentile (95% CI)	13.14 (NE, NE)	NE (11.14, NE)	13.14 (NE, NE)	NE (NE, NE)	
Median (95% CI)	13.14 (NE, NE)	NE (12.14, NE)	13.14 (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	13.14 (NE, NE)	NE (NE, NE)	13.14 (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 13.14	0.14, 12.86	0.14, 13.14	0.14, 12.71	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction.
MRI = Magnetic Resonance Imaging. CT = Computerized Tomography.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-sr-sub.sas V.03.05 Output file: t-dur-sr-tss.pdf 24AUG2023:12:41

Table 2.0502: Analysis of Duration of MRI/CT Splenic Response
Double-blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Subjects with Event		
Loss of spleen response, n(%)	2 (2.3%)	2 (2.1%)
Censor		
Subjects Censored, n(%)	84 (97.7%)	92 (97.9%)
Non-Responder: Censored at Randomization Date	55 (65.5%)	58 (63.0%)
No Loss of Response: Censored at Last MRI Spleen Assessment Date in DB phase (including up to 10 days after First Dose Date of OL phase)	29 (34.5%)	34 (37.0%)
Kaplan-Meier Estimate of Duration of Spleen Response (Weeks)		
25-percentile (95% CI)	13.14 (NE, NE)	NE (11.14, NE)
Median (95% CI)	13.14 (NE, NE)	NE (NE, NE)
75-percentile (95% CI)	13.14 (NE, NE)	NE (NE, NE)
Min, Max	0.14, 13.14	0.14, 12.86
Stratified Log-Rank Test p-value	0.34	
Adjusted Hazard Ratio (95% CI)	<0.01 (<0.01, NE)	
Unstratified Log-Rank Test p-value	0.16	
Unadjusted Hazard Ratio (95% CI)	<0.01 (<0.01, NE)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L).
Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
MRI = Magnetic Resonance Imaging. CT = Computerized Tomography.

Data Extracted: CRF data: 01JUL2019
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Table 2.0130: Analysis of Splenic Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-Label Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Spleen Volume (cm^3) at Baseline					
N	64	84	148	86	170
Mean (SD)	1975.2 (807.38)	2256.5 (1283.09)	2134.9 (1108.36)	1981.4 (776.14)	2117.3 (1063.27)
Median	1788.1	1932.9	1824.8	1788.1	1824.8
Q1, Q3	1406.1, 2572.3	1406.0, 2797.7	1406.1, 2715.2	1429.9, 2532.6	1429.9, 2628.5
Min, Max	352, 4027	686, 9022	352, 9022	352, 4027	352, 9022
Splenic Response Rate at Any Timepoint of Overall Exposed to MMB Period					
Responder, n(%)				40 (46.5%)	75 (44.1%)
95% Exact CI				0.3568, 0.5759	0.3652, 0.5192
Splenic Response Rate at Any Timepoint of Open-label Phase					
Subjects Ongoing and not Reach the 1st Assessment Timepoint in Open-label Phase, n(%)	0	0	0		
Subjects Discontinued or Reached the 1st Assessment Timepoint in Open-label Phase, n(%)	64 (100.0%)	84 (100.0%)	148 (100.0%)		
Responder, n(%)	38 (59.4%)	35 (41.7%)	73 (49.3%)		
95% Exact CI	0.4637, 0.7149	0.3100, 0.5294	0.4102, 0.5766		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Baseline is the last assessment prior to or on the date of randomization
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and did not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 01JUL2019

Table 2.0130: Analysis of Splenic Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-Label Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Week 24 in Open-label Phase					
Subjects ongoing and not reaching Week 24 in Open-label Phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 24 in Open-label Phase	64 (100.0%)	84 (100.0%)	148 (100.0%)		
Splenic Response Rate at Week 24 in Open-label Phase					
Responder, n(%)	29 (45.3%)	25 (29.8%)	54 (36.5%)		
95% Exact CI	0.3282, 0.5825	0.2027, 0.4073	0.2874, 0.4479		
Non-Responder, n(%)	35 (54.7%)	59 (70.2%)	94 (63.5%)		
Baseline Spleen Volume not available	0	0	0		
Spleen Volume at Week 24 not available	10 (15.6%)	17 (20.2%)	27 (18.2%)		
>0% Spleen Volume increase at Week 24	3 (4.7%)	8 (9.5%)	11 (7.4%)		
<35% Spleen Volume reduction from Baseline	25 (39.1%)	42 (50.0%)	67 (45.3%)		
Discontinuation early at Week 24	7 (10.9%)	13 (15.5%)	20 (13.5%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Baseline is the last assessment prior to or on the date of randomization
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and did not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

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Table 2.0130: Analysis of Splenic Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-Label Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Week 12 in Open-label Phase					
Subjects ongoing and not reaching Week 12 in Open-label Phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 12 in Open-label Phase	64 (100.0%)	84 (100.0%)	148 (100.0%)		
Splenic Response Rate at Week 12 in Open-label Phase					
Responder, n(%)	28 (43.8%)	26 (31.0%)	54 (36.5%)		
95% Exact CI	0.3137, 0.5672	0.2131, 0.4198	0.2874, 0.4479		
Non-Responder, n(%)	36 (56.3%)	58 (69.0%)	94 (63.5%)		
Baseline Spleen Volume not available	0	0	0		
Spleen Volume at Week 12 not available	6 (9.4%)	13 (15.5%)	19 (12.8%)		
>0% Spleen Volume increase at Week 12	6 (9.4%)	7 (8.3%)	13 (8.8%)		
<35% Spleen Volume reduction from Baseline	30 (46.9%)	45 (53.6%)	75 (50.7%)		
Discontinuation early at Week 12	2 (3.1%)	6 (7.1%)	8 (5.4%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Baseline is the last assessment prior to or on the date of randomization
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and did not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

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Table 2.0130: Analysis of Splenic Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-Label Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Week 36 in Open-label Phase					
Subjects ongoing and not reaching Week 36 in Open-label Phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 36 in Open-label Phase	64 (100.0%)	84 (100.0%)	148 (100.0%)		
Splenic Response Rate at Week 36 in Open-label Phase					
Responder, n(%)	24 (37.5%)	20 (23.8%)	44 (29.7%)		
95% Exact CI	0.2570, 0.5049	0.1519, 0.3435	0.2250, 0.3779		
Non-Responder, n(%)	40 (62.5%)	64 (76.2%)	104 (70.3%)		
Baseline Spleen Volume not available	0	0	0		
Spleen Volume at Week 36 not available	18 (28.1%)	27 (32.1%)	45 (30.4%)		
>0% Spleen Volume increase at Week 36	4 (6.3%)	9 (10.7%)	13 (8.8%)		
<35% Spleen Volume reduction from Baseline	22 (34.4%)	37 (44.0%)	59 (39.9%)		
Discontinuation early at Week 36	11 (17.2%)	20 (23.8%)	31 (20.9%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Baseline is the last assessment prior to or on the date of randomization
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and did not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

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Table 2.0130: Analysis of Splenic Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-Label Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Week 48 in Open-label Phase					
Subjects ongoing and not reaching Week 48 in Open-label Phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 48 in Open-label Phase	64 (100.0%)	84 (100.0%)	148 (100.0%)		
Splenic Response Rate at Week 48 in Open-label Phase					
Responder, n(%)	23 (35.9%)	18 (21.4%)	41 (27.7%)		
95% Exact CI	0.2432, 0.4890	0.1322, 0.3174	0.2067, 0.3565		
Non-Responder, n(%)	41 (64.1%)	66 (78.6%)	107 (72.3%)		
Baseline Spleen Volume not available	0	0	0		
Spleen Volume at Week 48 not available	23 (35.9%)	35 (41.7%)	58 (39.2%)		
>0% Spleen Volume increase at Week 48	2 (3.1%)	7 (8.3%)	9 (6.1%)		
<35% Spleen Volume reduction from Baseline	18 (28.1%)	31 (36.9%)	49 (33.1%)		
Discontinuation early at Week 48	18 (28.1%)	29 (34.5%)	47 (31.8%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Baseline is the last assessment prior to or on the date of randomization
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and did not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

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Table 2.0130: Analysis of Splenic Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-Label Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Week 60 in Open-label Phase					
Subjects ongoing and not reaching Week 60 in Open-label Phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 60 in Open-label Phase	64 (100.0%)	84 (100.0%)	148 (100.0%)		
Splenic Response Rate at Week 60 in Open-label Phase					
Responder, n(%)	21 (32.8%)	17 (20.2%)	38 (25.7%)		
95% Exact CI	0.2159, 0.4569	0.1225, 0.3041	0.1885, 0.3350		
Non-Responder, n(%)	43 (67.2%)	67 (79.8%)	110 (74.3%)		
Baseline Spleen Volume not available	0	0	0		
Spleen Volume at Week 60 not available	28 (43.8%)	39 (46.4%)	67 (45.3%)		
>0% Spleen Volume increase at Week 60	1 (1.6%)	5 (6.0%)	6 (4.1%)		
<35% Spleen Volume reduction from Baseline	15 (23.4%)	28 (33.3%)	43 (29.1%)		
Discontinuation early at Week 60	24 (37.5%)	37 (44.0%)	61 (41.2%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Baseline is the last assessment prior to or on the date of randomization
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and did not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

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Table 2.0130: Analysis of Splenic Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-Label Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Week 72 in Open-label Phase					
Subjects ongoing and not reaching Week 72 in Open-label Phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 72 in Open-label Phase	64 (100.0%)	84 (100.0%)	148 (100.0%)		
Splenic Response Rate at Week 72 in Open-label Phase					
Responder, n(%)	16 (25.0%)	17 (20.2%)	33 (22.3%)		
95% Exact CI	0.1502, 0.3740	0.1225, 0.3041	0.1587, 0.2986		
Non-Responder, n(%)	48 (75.0%)	67 (79.8%)	115 (77.7%)		
Baseline Spleen Volume not available	0	0	0		
Spleen Volume at Week 72 not available	33 (51.6%)	46 (54.8%)	79 (53.4%)		
>0% Spleen Volume increase at Week 72	0	3 (3.6%)	3 (2.0%)		
<35% Spleen Volume reduction from Baseline	15 (23.4%)	21 (25.0%)	36 (24.3%)		
Discontinuation early at Week 72	31 (48.4%)	42 (50.0%)	73 (49.3%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Baseline is the last assessment prior to or on the date of randomization
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and did not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 01JUL2019

Table 2.0130: Analysis of Splenic Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-Label Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Week 84 in Open-label Phase					
Subjects ongoing and not reaching Week 84 in Open-label Phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 84 in Open-label Phase	64 (100.0%)	84 (100.0%)	148 (100.0%)		
Splenic Response Rate at Week 84 in Open-label Phase					
Responder, n(%)	14 (21.9%)	12 (14.3%)	26 (17.6%)		
95% Exact CI	0.1251, 0.3397	0.0761, 0.2362	0.1181, 0.2467		
Non-Responder, n(%)	50 (78.1%)	72 (85.7%)	122 (82.4%)		
Baseline Spleen Volume not available	0	0	0		
Spleen Volume at Week 84 not available	39 (60.9%)	55 (65.5%)	94 (63.5%)		
>0% Spleen Volume increase at Week 84	1 (1.6%)	5 (6.0%)	6 (4.1%)		
<35% Spleen Volume reduction from Baseline	11 (17.2%)	17 (20.2%)	28 (18.9%)		
Discontinuation early at Week 84	33 (51.6%)	48 (57.1%)	81 (54.7%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Baseline is the last assessment prior to or on the date of randomization
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and did not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 01JUL2019

Table 2.0130: Analysis of Splenic Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-Label Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Week 96 in Open-label Phase					
Subjects ongoing and not reaching Week 96 in Open-label Phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 96 in Open-label Phase	64 (100.0%)	84 (100.0%)	148 (100.0%)		
Splenic Response Rate at Week 96 in Open-label Phase					
Responder, n(%)	15 (23.4%)	13 (15.5%)	28 (18.9%)		
95% Exact CI	0.1375, 0.3569	0.0851, 0.2501	0.1295, 0.2617		
Non-Responder, n(%)	49 (76.6%)	71 (84.5%)	120 (81.1%)		
Baseline Spleen Volume not available	0	0	0		
Spleen Volume at Week 96 not available	41 (64.1%)	54 (64.3%)	95 (64.2%)		
>0% Spleen Volume increase at Week 96	1 (1.6%)	7 (8.3%)	8 (5.4%)		
<35% Spleen Volume reduction from Baseline	8 (12.5%)	17 (20.2%)	25 (16.9%)		
Discontinuation early at Week 96	36 (56.3%)	51 (60.7%)	87 (58.8%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Baseline is the last assessment prior to or on the date of randomization
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and did not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

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Table 2.0130: Analysis of Splenic Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-Label Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Week 108 in Open-label Phase					
Subjects ongoing and not reaching Week 108 in Open-label Phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 108 in Open-label Phase	64 (100.0%)	84 (100.0%)	148 (100.0%)		
Splenic Response Rate at Week 108 in Open-label Phase					
Responder, n(%)	11 (17.2%)	12 (14.3%)	23 (15.5%)		
95% Exact CI	0.0890, 0.2868	0.0761, 0.2362	0.1011, 0.2240		
Non-Responder, n(%)	53 (82.8%)	72 (85.7%)	125 (84.5%)		
Baseline Spleen Volume not available	0	0	0		
Spleen Volume at Week 108 not available	45 (70.3%)	57 (67.9%)	102 (68.9%)		
>0% Spleen Volume increase at Week 108	0	7 (8.3%)	7 (4.7%)		
<35% Spleen Volume reduction from Baseline	8 (12.5%)	15 (17.9%)	23 (15.5%)		
Discontinuation early at Week 108	40 (62.5%)	51 (60.7%)	91 (61.5%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Baseline is the last assessment prior to or on the date of randomization
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and did not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 01JUL2019
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Table 2.0130: Analysis of Splenic Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-Label Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Week 120 in Open-label Phase					
Subjects ongoing and not reaching Week 120 in Open-label Phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 120 in Open-label Phase	64 (100.0%)	84 (100.0%)	148 (100.0%)		
Splenic Response Rate at Week 120 in Open-label Phase					
Responder, n(%)	12 (18.8%)	11 (13.1%)	23 (15.5%)		
95% Exact CI	0.1008, 0.3046	0.0672, 0.2222	0.1011, 0.2240		
Non-Responder, n(%)	52 (81.3%)	73 (86.9%)	125 (84.5%)		
Baseline Spleen Volume not available	0	0	0		
Spleen Volume at Week 120 not available	46 (71.9%)	61 (72.6%)	107 (72.3%)		
>0% Spleen Volume increase at Week 120	0	4 (4.8%)	4 (2.7%)		
<35% Spleen Volume reduction from Baseline	6 (9.4%)	12 (14.3%)	18 (12.2%)		
Discontinuation early at Week 120	43 (67.2%)	56 (66.7%)	99 (66.9%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Baseline is the last assessment prior to or on the date of randomization
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and did not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 01JUL2019
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Table 2.0130: Analysis of Splenic Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-Label Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Week 132 in Open-label Phase					
Subjects ongoing and not reaching Week 132 in Open-label Phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 132 in Open-label Phase	64 (100.0%)	84 (100.0%)	148 (100.0%)		
Splenic Response Rate at Week 132 in Open-label Phase					
Responder, n(%)	11 (17.2%)	4 (4.8%)	15 (10.1%)		
95% Exact CI	0.0890, 0.2868	0.0131, 0.1175	0.0578, 0.1617		
Non-Responder, n(%)	53 (82.8%)	80 (95.2%)	133 (89.9%)		
Baseline Spleen Volume not available	0	0	0		
Spleen Volume at Week 132 not available	49 (76.6%)	68 (81.0%)	117 (79.1%)		
>0% Spleen Volume increase at Week 132	0	5 (6.0%)	5 (3.4%)		
<35% Spleen Volume reduction from Baseline	4 (6.3%)	12 (14.3%)	16 (10.8%)		
Discontinuation early at Week 132	45 (70.3%)	59 (70.2%)	104 (70.3%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Baseline is the last assessment prior to or on the date of randomization
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and did not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 01JUL2019
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Table 2.0130: Analysis of Splenic Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-Label Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Week 144 in Open-label Phase					
Subjects ongoing and not reaching Week 144 in Open-label Phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 144 in Open-label Phase	64 (100.0%)	84 (100.0%)	148 (100.0%)		
Splenic Response Rate at Week 144 in Open-label Phase					
Responder, n(%)	6 (9.4%)	3 (3.6%)	9 (6.1%)		
95% Exact CI	0.0352, 0.1930	0.0074, 0.1008	0.0282, 0.1123		
Non-Responder, n(%)	58 (90.6%)	81 (96.4%)	139 (93.9%)		
Baseline Spleen Volume not available	0	0	0		
Spleen Volume at Week 144 not available	54 (84.4%)	75 (89.3%)	129 (87.2%)		
>0% Spleen Volume increase at Week 144	0	2 (2.4%)	2 (1.4%)		
<35% Spleen Volume reduction from Baseline	4 (6.3%)	6 (7.1%)	10 (6.8%)		
Discontinuation early at Week 144	50 (78.1%)	70 (83.3%)	120 (81.1%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Baseline is the last assessment prior to or on the date of randomization
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and did not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

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Table 2.0130: Analysis of Splenic Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-Label Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Week 156 in Open-label Phase					
Subjects ongoing and not reaching Week 156 in Open-label Phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 156 in Open-label Phase	64 (100.0%)	84 (100.0%)	148 (100.0%)		
Splenic Response Rate at Week 156 in Open-label Phase					
Responder, n(%)	3 (4.7%)	1 (1.2%)	4 (2.7%)		
95% Exact CI	0.0098, 0.1309	0.0003, 0.0646	0.0074, 0.0678		
Non-Responder, n(%)	61 (95.3%)	83 (98.8%)	144 (97.3%)		
Baseline Spleen Volume not available	0	0	0		
Spleen Volume at Week 156 not available	58 (90.6%)	81 (96.4%)	139 (93.9%)		
>0% Spleen Volume increase at Week 156	1 (1.6%)	1 (1.2%)	2 (1.4%)		
<35% Spleen Volume reduction from Baseline	3 (4.7%)	2 (2.4%)	5 (3.4%)		
Discontinuation early at Week 156	55 (85.9%)	76 (90.5%)	131 (88.5%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Baseline is the last assessment prior to or on the date of randomization
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and did not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 01JUL2019
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Table 2.0130: Analysis of Splenic Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-Label Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Week 168 in Open-label Phase					
Subjects ongoing and not reaching Week 168 in Open-label Phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 168 in Open-label Phase	64 (100.0%)	84 (100.0%)	148 (100.0%)		
Splenic Response Rate at Week 168 in Open-label Phase					
Responder, n(%)	2 (3.1%)	1 (1.2%)	3 (2.0%)		
95% Exact CI	0.0038, 0.1084	0.0003, 0.0646	0.0042, 0.0581		
Non-Responder, n(%)	62 (96.9%)	83 (98.8%)	145 (98.0%)		
Baseline Spleen Volume not available	0	0	0		
Spleen Volume at Week 168 not available	59 (92.2%)	83 (98.8%)	142 (95.9%)		
>0% Spleen Volume increase at Week 168	0	0	0		
<35% Spleen Volume reduction from Baseline	3 (4.7%)	0	3 (2.0%)		
Discontinuation early at Week 168	58 (90.6%)	81 (96.4%)	139 (93.9%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Baseline is the last assessment prior to or on the date of randomization
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and did not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 01JUL2019
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Table 2.0129: Analysis of Splenic Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-Label Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Spleen Volume (cm^3) at Baseline					
N	64	84	148	86	170
Mean (SD)	1975.2 (807.38)	1735.9 (1184.88)	1839.4 (1042.22)	1981.4 (776.14)	1860.1 (1003.81)
Median	1788.1	1488.9	1635.0	1788.1	1666.3
Q1, Q3	1406.1, 2572.3	950.5, 2110.8	1091.1, 2334.0	1429.9, 2532.6	1147.1, 2474.1
Min, Max	352, 4027	336, 8288	336, 8288	352, 4027	336, 8288
Splenic Response Rate at Any Timepoint of Overall Exposed to MMB Period					
Responder, n(%)				40 (46.5%)	52 (30.6%)
95% Exact CI				0.3568, 0.5759	0.2376, 0.3811
Splenic Response Rate at Any Timepoint of Open-label Phase					
Subjects Ongoing and not Reach the 1st Assessment Timepoint in Open-label Phase, n(%)	0	0	0		
Subjects Discontinued or Reached the 1st Assessment Timepoint in Open-label Phase, n(%)	64 (100.0%)	84 (100.0%)	148 (100.0%)		
Responder, n(%)	38 (59.4%)	12 (14.3%)	50 (33.8%)		
95% Exact CI	0.4637, 0.7149	0.0761, 0.2362	0.2622, 0.4201		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
For Switch (RUX->MMB) group, the baseline is the last assessment prior to or on the date of the 1st MMB dose in the OL phase.
For Continuing (MMB->MMB), the baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and did not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 01JUL2019

Table 2.0129: Analysis of Splenic Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-Label Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Week 24 in Open-label Phase					
Subjects ongoing and not reaching Week 24 in Open-label Phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 24 in Open-label Phase	64 (100.0%)	84 (100.0%)	148 (100.0%)		
Splenic Response Rate at Week 24 in Open-label Phase					
Responder, n(%)	29 (45.3%)	2 (2.4%)	31 (20.9%)		
95% Exact CI	0.3282, 0.5825	0.0029, 0.0834	0.1470, 0.2839		
Non-Responder, n(%)	35 (54.7%)	82 (97.6%)	117 (79.1%)		
Baseline Spleen Volume not available	0	0	0		
Spleen Volume at Week 24 not available	10 (15.6%)	17 (20.2%)	27 (18.2%)		
>0% Spleen Volume increase at Week 24	3 (4.7%)	34 (40.5%)	37 (25.0%)		
<35% Spleen Volume reduction from Baseline	25 (39.1%)	65 (77.4%)	90 (60.8%)		
Discontinuation early at Week 24	7 (10.9%)	13 (15.5%)	20 (13.5%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
For Switch (RUX->MMB) group, the baseline is the last assessment prior to or on the date of the 1st MMB dose in the OL phase.
For Continuing (MMB->MMB), the baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and did not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 01JUL2019

Table 2.0129: Analysis of Splenic Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-Label Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Week 12 in Open-label Phase					
Subjects ongoing and not reaching Week 12 in Open-label Phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 12 in Open-label Phase	64 (100.0%)	84 (100.0%)	148 (100.0%)		
Splenic Response Rate at Week 12 in Open-label Phase					
Responder, n(%)	28 (43.8%)	2 (2.4%)	30 (20.3%)		
95% Exact CI	0.3137, 0.5672	0.0029, 0.0834	0.1411, 0.2766		
Non-Responder, n(%)	36 (56.3%)	82 (97.6%)	118 (79.7%)		
Baseline Spleen Volume not available	0	0	0		
Spleen Volume at Week 12 not available	6 (9.4%)	13 (15.5%)	19 (12.8%)		
>0% Spleen Volume increase at Week 12	6 (9.4%)	37 (44.0%)	43 (29.1%)		
<35% Spleen Volume reduction from Baseline	30 (46.9%)	69 (82.1%)	99 (66.9%)		
Discontinuation early at Week 12	2 (3.1%)	6 (7.1%)	8 (5.4%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
For Switch (RUX->MMB) group, the baseline is the last assessment prior to or on the date of the 1st MMB dose in the OL phase.
For Continuing (MMB->MMB), the baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and did not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 01JUL2019

Table 2.0129: Analysis of Splenic Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-Label Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Week 36 in Open-label Phase					
Subjects ongoing and not reaching Week 36 in Open-label Phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 36 in Open-label Phase	64 (100.0%)	84 (100.0%)	148 (100.0%)		
Splenic Response Rate at Week 36 in Open-label Phase					
Responder, n(%)	24 (37.5%)	5 (6.0%)	29 (19.6%)		
95% Exact CI	0.2570, 0.5049	0.0196, 0.1335	0.1353, 0.2691		
Non-Responder, n(%)	40 (62.5%)	79 (94.0%)	119 (80.4%)		
Baseline Spleen Volume not available	0	0	0		
Spleen Volume at Week 36 not available	18 (28.1%)	27 (32.1%)	45 (30.4%)		
>0% Spleen Volume increase at Week 36	4 (6.3%)	32 (38.1%)	36 (24.3%)		
<35% Spleen Volume reduction from Baseline	22 (34.4%)	52 (61.9%)	74 (50.0%)		
Discontinuation early at Week 36	11 (17.2%)	20 (23.8%)	31 (20.9%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
For Switch (RUX->MMB) group, the baseline is the last assessment prior to or on the date of the 1st MMB dose in the OL phase.
For Continuing (MMB->MMB), the baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and did not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 01JUL2019

Table 2.0129: Analysis of Splenic Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-Label Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Week 48 in Open-label Phase					
Subjects ongoing and not reaching Week 48 in Open-label Phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 48 in Open-label Phase	64 (100.0%)	84 (100.0%)	148 (100.0%)		
Splenic Response Rate at Week 48 in Open-label Phase					
Responder, n(%)	23 (35.9%)	5 (6.0%)	28 (18.9%)		
95% Exact CI	0.2432, 0.4890	0.0196, 0.1335	0.1295, 0.2617		
Non-Responder, n(%)	41 (64.1%)	79 (94.0%)	120 (81.1%)		
Baseline Spleen Volume not available	0	0	0		
Spleen Volume at Week 48 not available	23 (35.9%)	35 (41.7%)	58 (39.2%)		
>0% Spleen Volume increase at Week 48	2 (3.1%)	26 (31.0%)	28 (18.9%)		
<35% Spleen Volume reduction from Baseline	18 (28.1%)	44 (52.4%)	62 (41.9%)		
Discontinuation early at Week 48	18 (28.1%)	29 (34.5%)	47 (31.8%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
For Switch (RUX->MMB) group, the baseline is the last assessment prior to or on the date of the 1st MMB dose in the OL phase.
For Continuing (MMB->MMB), the baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and did not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 01JUL2019

Table 2.0129: Analysis of Splenic Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-Label Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Week 60 in Open-label Phase					
Subjects ongoing and not reaching Week 60 in Open-label Phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 60 in Open-label Phase	64 (100.0%)	84 (100.0%)	148 (100.0%)		
Splenic Response Rate at Week 60 in Open-label Phase					
Responder, n(%)	21 (32.8%)	4 (4.8%)	25 (16.9%)		
95% Exact CI	0.2159, 0.4569	0.0131, 0.1175	0.1124, 0.2392		
Non-Responder, n(%)	43 (67.2%)	80 (95.2%)	123 (83.1%)		
Baseline Spleen Volume not available	0	0	0		
Spleen Volume at Week 60 not available	28 (43.8%)	39 (46.4%)	67 (45.3%)		
>0% Spleen Volume increase at Week 60	1 (1.6%)	19 (22.6%)	20 (13.5%)		
<35% Spleen Volume reduction from Baseline	15 (23.4%)	41 (48.8%)	56 (37.8%)		
Discontinuation early at Week 60	24 (37.5%)	37 (44.0%)	61 (41.2%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
For Switch (RUX->MMB) group, the baseline is the last assessment prior to or on the date of the 1st MMB dose in the OL phase.
For Continuing (MMB->MMB), the baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and did not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 01JUL2019

Table 2.0129: Analysis of Splenic Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-Label Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Week 72 in Open-label Phase					
Subjects ongoing and not reaching Week 72 in Open-label Phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 72 in Open-label Phase	64 (100.0%)	84 (100.0%)	148 (100.0%)		
Splenic Response Rate at Week 72 in Open-label Phase					
Responder, n(%)	16 (25.0%)	5 (6.0%)	21 (14.2%)		
95% Exact CI	0.1502, 0.3740	0.0196, 0.1335	0.0900, 0.2087		
Non-Responder, n(%)	48 (75.0%)	79 (94.0%)	127 (85.8%)		
Baseline Spleen Volume not available	0	0	0		
Spleen Volume at Week 72 not available	33 (51.6%)	46 (54.8%)	79 (53.4%)		
>0% Spleen Volume increase at Week 72	0	16 (19.0%)	16 (10.8%)		
<35% Spleen Volume reduction from Baseline	15 (23.4%)	33 (39.3%)	48 (32.4%)		
Discontinuation early at Week 72	31 (48.4%)	42 (50.0%)	73 (49.3%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
For Switch (RUX->MMB) group, the baseline is the last assessment prior to or on the date of the 1st MMB dose in the OL phase.
For Continuing (MMB->MMB), the baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and did not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 01JUL2019

Table 2.0129: Analysis of Splenic Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-Label Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Week 84 in Open-label Phase					
Subjects ongoing and not reaching Week 84 in Open-label Phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 84 in Open-label Phase	64 (100.0%)	84 (100.0%)	148 (100.0%)		
Splenic Response Rate at Week 84 in Open-label Phase					
Responder, n(%)	14 (21.9%)	3 (3.6%)	17 (11.5%)		
95% Exact CI	0.1251, 0.3397	0.0074, 0.1008	0.0684, 0.1775		
Non-Responder, n(%)	50 (78.1%)	81 (96.4%)	131 (88.5%)		
Baseline Spleen Volume not available	0	0	0		
Spleen Volume at Week 84 not available	39 (60.9%)	55 (65.5%)	94 (63.5%)		
>0% Spleen Volume increase at Week 84	1 (1.6%)	11 (13.1%)	12 (8.1%)		
<35% Spleen Volume reduction from Baseline	11 (17.2%)	26 (31.0%)	37 (25.0%)		
Discontinuation early at Week 84	33 (51.6%)	48 (57.1%)	81 (54.7%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
For Switch (RUX->MMB) group, the baseline is the last assessment prior to or on the date of the 1st MMB dose in the OL phase.
For Continuing (MMB->MMB), the baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and did not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 01JUL2019

Table 2.0129: Analysis of Splenic Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-Label Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Week 96 in Open-label Phase					
Subjects ongoing and not reaching Week 96 in Open-label Phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 96 in Open-label Phase	64 (100.0%)	84 (100.0%)	148 (100.0%)		
Splenic Response Rate at Week 96 in Open-label Phase					
Responder, n(%)	15 (23.4%)	5 (6.0%)	20 (13.5%)		
95% Exact CI	0.1375, 0.3569	0.0196, 0.1335	0.0845, 0.2010		
Non-Responder, n(%)	49 (76.6%)	79 (94.0%)	128 (86.5%)		
Baseline Spleen Volume not available	0	0	0		
Spleen Volume at Week 96 not available	41 (64.1%)	54 (64.3%)	95 (64.2%)		
>0% Spleen Volume increase at Week 96	1 (1.6%)	16 (19.0%)	17 (11.5%)		
<35% Spleen Volume reduction from Baseline	8 (12.5%)	25 (29.8%)	33 (22.3%)		
Discontinuation early at Week 96	36 (56.3%)	51 (60.7%)	87 (58.8%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
For Switch (RUX->MMB) group, the baseline is the last assessment prior to or on the date of the 1st MMB dose in the OL phase.
For Continuing (MMB->MMB), the baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and did not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 01JUL2019

Table 2.0129: Analysis of Splenic Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-Label Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Week 108 in Open-label Phase					
Subjects ongoing and not reaching Week 108 in Open-label Phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 108 in Open-label Phase	64 (100.0%)	84 (100.0%)	148 (100.0%)		
Splenic Response Rate at Week 108 in Open-label Phase					
Responder, n(%)	11 (17.2%)	5 (6.0%)	16 (10.8%)		
95% Exact CI	0.0890, 0.2868	0.0196, 0.1335	0.0631, 0.1696		
Non-Responder, n(%)	53 (82.8%)	79 (94.0%)	132 (89.2%)		
Baseline Spleen Volume not available	0	0	0		
Spleen Volume at Week 108 not available	45 (70.3%)	57 (67.9%)	102 (68.9%)		
>0% Spleen Volume increase at Week 108	0	13 (15.5%)	13 (8.8%)		
<35% Spleen Volume reduction from Baseline	8 (12.5%)	22 (26.2%)	30 (20.3%)		
Discontinuation early at Week 108	40 (62.5%)	51 (60.7%)	91 (61.5%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
For Switch (RUX->MMB) group, the baseline is the last assessment prior to or on the date of the 1st MMB dose in the OL phase.
For Continuing (MMB->MMB), the baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and did not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 01JUL2019

Table 2.0129: Analysis of Splenic Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-Label Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Week 120 in Open-label Phase					
Subjects ongoing and not reaching Week 120 in Open-label Phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 120 in Open-label Phase	64 (100.0%)	84 (100.0%)	148 (100.0%)		
Splenic Response Rate at Week 120 in Open-label Phase					
Responder, n(%)	12 (18.8%)	5 (6.0%)	17 (11.5%)		
95% Exact CI	0.1008, 0.3046	0.0196, 0.1335	0.0684, 0.1775		
Non-Responder, n(%)	52 (81.3%)	79 (94.0%)	131 (88.5%)		
Baseline Spleen Volume not available	0	0	0		
Spleen Volume at Week 120 not available	46 (71.9%)	61 (72.6%)	107 (72.3%)		
>0% Spleen Volume increase at Week 120	0	9 (10.7%)	9 (6.1%)		
<35% Spleen Volume reduction from Baseline	6 (9.4%)	18 (21.4%)	24 (16.2%)		
Discontinuation early at Week 120	43 (67.2%)	56 (66.7%)	99 (66.9%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
For Switch (RUX->MMB) group, the baseline is the last assessment prior to or on the date of the 1st MMB dose in the OL phase.
For Continuing (MMB->MMB), the baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and did not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 01JUL2019

Table 2.0129: Analysis of Splenic Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-Label Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Week 132 in Open-label Phase					
Subjects ongoing and not reaching Week 132 in Open-label Phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 132 in Open-label Phase	64 (100.0%)	84 (100.0%)	148 (100.0%)		
Splenic Response Rate at Week 132 in Open-label Phase					
Responder, n(%)	11 (17.2%)	0	11 (7.4%)		
95% Exact CI	0.0890, 0.2868	0.0000, 0.0430	0.0377, 0.1291		
Non-Responder, n(%)	53 (82.8%)	84 (100.0%)	137 (92.6%)		
Baseline Spleen Volume not available	0	0	0		
Spleen Volume at Week 132 not available	49 (76.6%)	68 (81.0%)	117 (79.1%)		
>0% Spleen Volume increase at Week 132	0	12 (14.3%)	12 (8.1%)		
<35% Spleen Volume reduction from Baseline	4 (6.3%)	16 (19.0%)	20 (13.5%)		
Discontinuation early at Week 132	45 (70.3%)	59 (70.2%)	104 (70.3%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
For Switch (RUX->MMB) group, the baseline is the last assessment prior to or on the date of the 1st MMB dose in the OL phase.
For Continuing (MMB->MMB), the baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and did not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 01JUL2019

Table 2.0129: Analysis of Splenic Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-Label Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Week 144 in Open-label Phase					
Subjects ongoing and not reaching Week 144 in Open-label Phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 144 in Open-label Phase	64 (100.0%)	84 (100.0%)	148 (100.0%)		
Splenic Response Rate at Week 144 in Open-label Phase					
Responder, n(%)	6 (9.4%)	0	6 (4.1%)		
95% Exact CI	0.0352, 0.1930	0.0000, 0.0430	0.0150, 0.0861		
Non-Responder, n(%)	58 (90.6%)	84 (100.0%)	142 (95.9%)		
Baseline Spleen Volume not available	0	0	0		
Spleen Volume at Week 144 not available	54 (84.4%)	75 (89.3%)	129 (87.2%)		
>0% Spleen Volume increase at Week 144	0	7 (8.3%)	7 (4.7%)		
<35% Spleen Volume reduction from Baseline	4 (6.3%)	9 (10.7%)	13 (8.8%)		
Discontinuation early at Week 144	50 (78.1%)	70 (83.3%)	120 (81.1%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
For Switch (RUX->MMB) group, the baseline is the last assessment prior to or on the date of the 1st MMB dose in the OL phase.
For Continuing (MMB->MMB), the baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and did not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 01JUL2019

Table 2.0129: Analysis of Splenic Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-Label Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Week 156 in Open-label Phase					
Subjects ongoing and not reaching Week 156 in Open-label Phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 156 in Open-label Phase	64 (100.0%)	84 (100.0%)	148 (100.0%)		
Splenic Response Rate at Week 156 in Open-label Phase					
Responder, n(%)	3 (4.7%)	0	3 (2.0%)		
95% Exact CI	0.0098, 0.1309	0.0000, 0.0430	0.0042, 0.0581		
Non-Responder, n(%)	61 (95.3%)	84 (100.0%)	145 (98.0%)		
Baseline Spleen Volume not available	0	0	0		
Spleen Volume at Week 156 not available	58 (90.6%)	81 (96.4%)	139 (93.9%)		
>0% Spleen Volume increase at Week 156	1 (1.6%)	2 (2.4%)	3 (2.0%)		
<35% Spleen Volume reduction from Baseline	3 (4.7%)	3 (3.6%)	6 (4.1%)		
Discontinuation early at Week 156	55 (85.9%)	76 (90.5%)	131 (88.5%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
For Switch (RUX->MMB) group, the baseline is the last assessment prior to or on the date of the 1st MMB dose in the OL phase.
For Continuing (MMB->MMB), the baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and did not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 01JUL2019

Table 2.0129: Analysis of Splenic Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-Label Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	MMB in DB (N=86)	Total (N=170)
Week 168 in Open-label Phase					
Subjects ongoing and not reaching Week 168 in Open-label Phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 168 in Open-label Phase	64 (100.0%)	84 (100.0%)	148 (100.0%)		
Splenic Response Rate at Week 168 in Open-label Phase					
Responder, n(%)	2 (3.1%)	0	2 (1.4%)		
95% Exact CI	0.0038, 0.1084	0.0000, 0.0430	0.0016, 0.0480		
Non-Responder, n(%)	62 (96.9%)	84 (100.0%)	146 (98.6%)		
Baseline Spleen Volume not available	0	0	0		
Spleen Volume at Week 168 not available	59 (92.2%)	83 (98.8%)	142 (95.9%)		
>0% Spleen Volume increase at Week 168	0	0	0		
<35% Spleen Volume reduction from Baseline	3 (4.7%)	1 (1.2%)	4 (2.7%)		
Discontinuation early at Week 168	58 (90.6%)	81 (96.4%)	139 (93.9%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
For Switch (RUX->MMB) group, the baseline is the last assessment prior to or on the date of the 1st MMB dose in the OL phase.
For Continuing (MMB->MMB), the baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and did not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

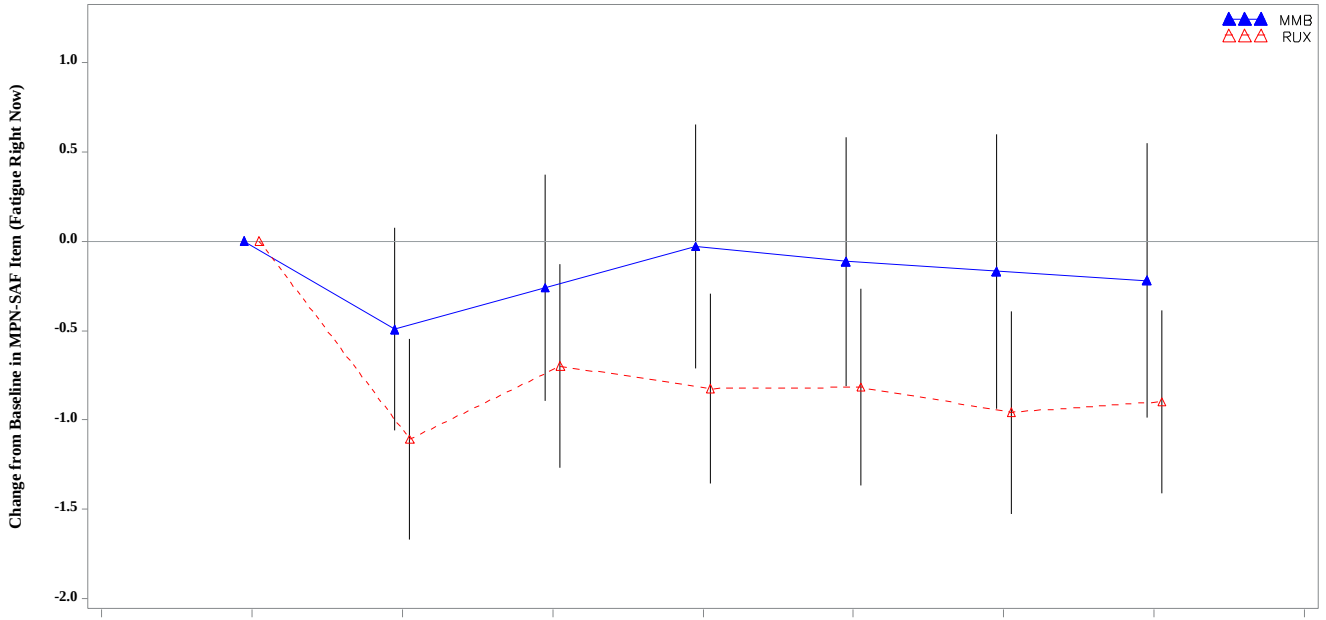
Data Extracted: CRF data: 01JUL2019

1.4 Symptomansprechen

1.4.1 MPN-SAF

Figure 2.3501: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Individual MPN-SAF Items over time
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=BFI01-Fatigue Right Now



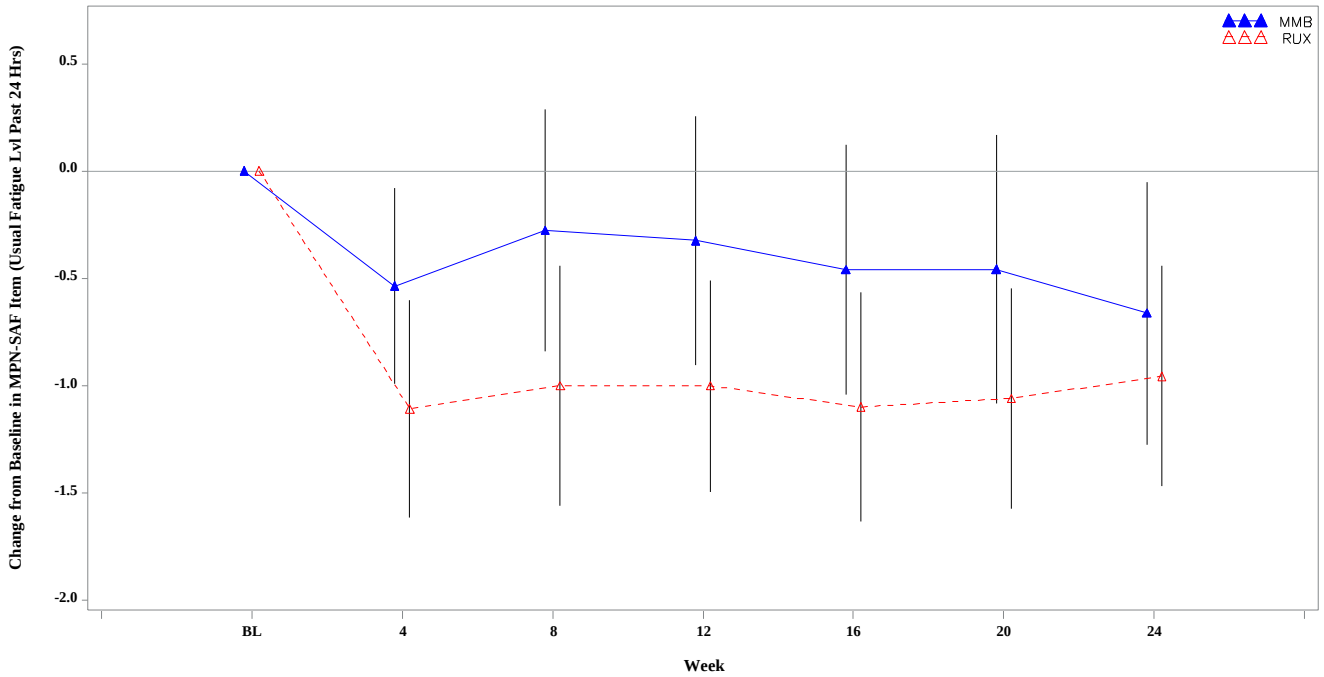
MMB	(n)	77	71	65	65	61	59	59
RUX	(n)	76	75	73	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-db.pdf 30AUG2023:12:29

Figure 2.3501: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Individual MPN-SAF Items over time
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=BFI01-Usual Fatigue Lvl Past 24 Hrs



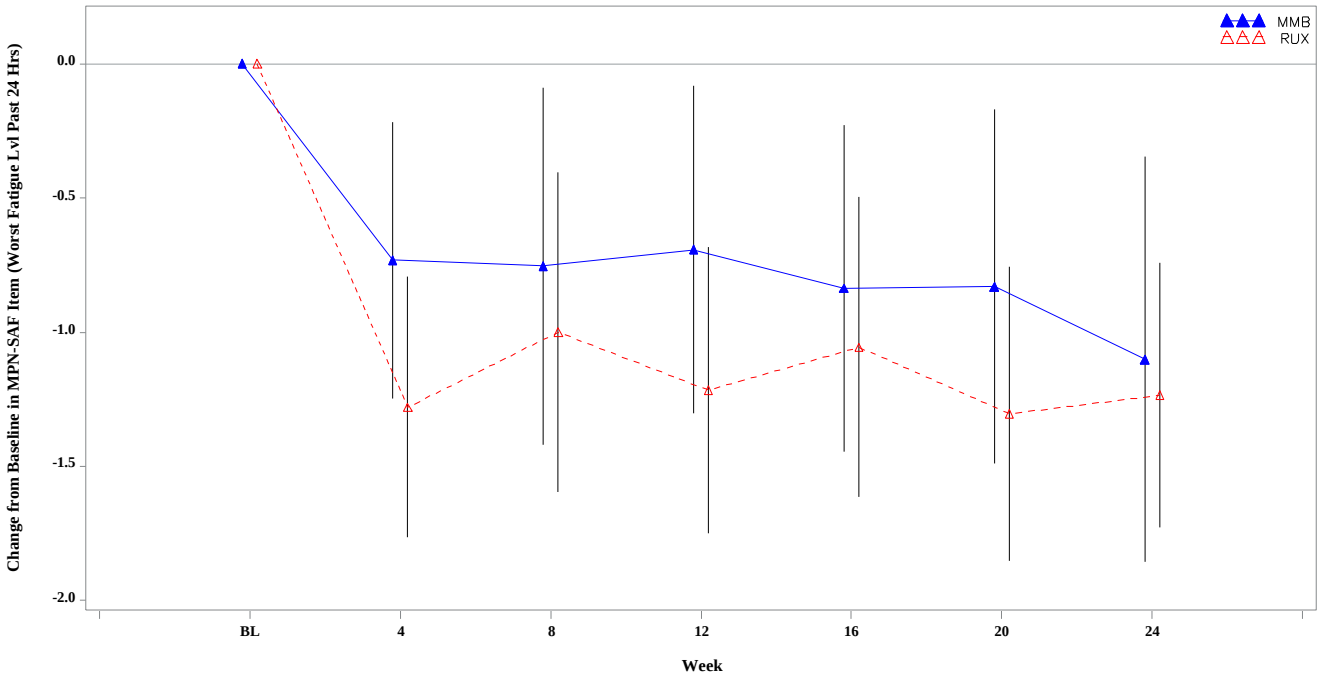
MMB	(n)	77	71	65	65	61	59	59
RUX	(n)	76	75	73	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-db.pdf 30AUG2023:12:29

Figure 2.3501: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Individual MPN-SAF Items over time
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=BFI01-Worst Fatigue Lvl Past 24 Hrs



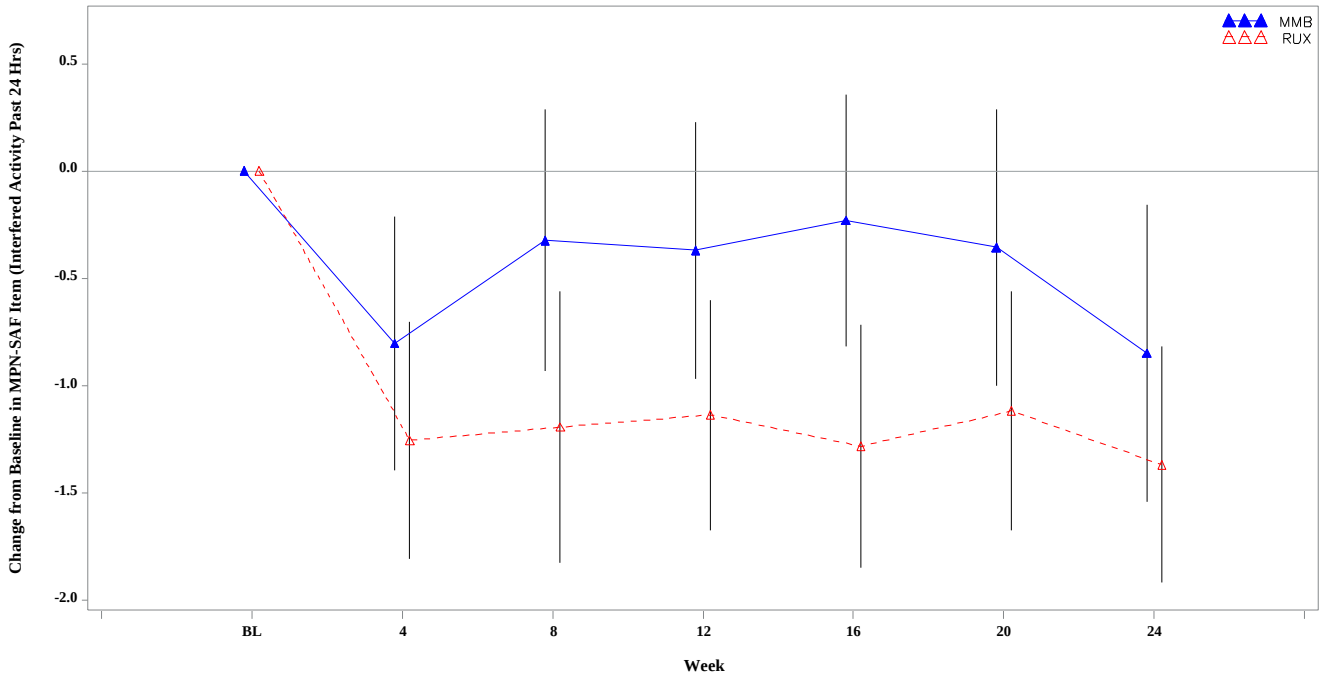
MMB	(n)	77	71	65	65	61	59	59
RUX	(n)	76	75	73	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-db.pdf 30AUG2023:12:29

Figure 2.3501: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Individual MPN-SAF Items over time
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=BFI01-Interfered Activity Past 24 Hrs



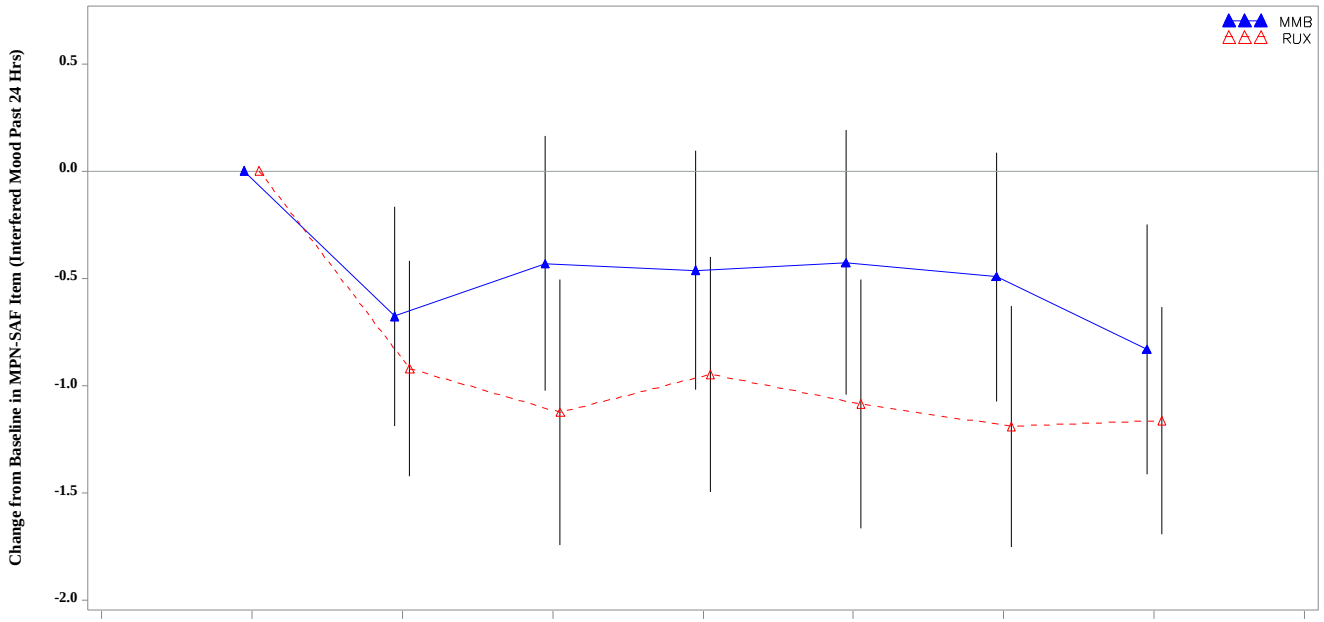
MMB	(n)	77	71	65	65	61	59	59
RUX	(n)	76	75	73	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-db.pdf 30AUG2023:12:29

Figure 2.3501: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Individual MPN-SAF Items over time
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=BFI01-Interfered Mood Past 24 Hrs



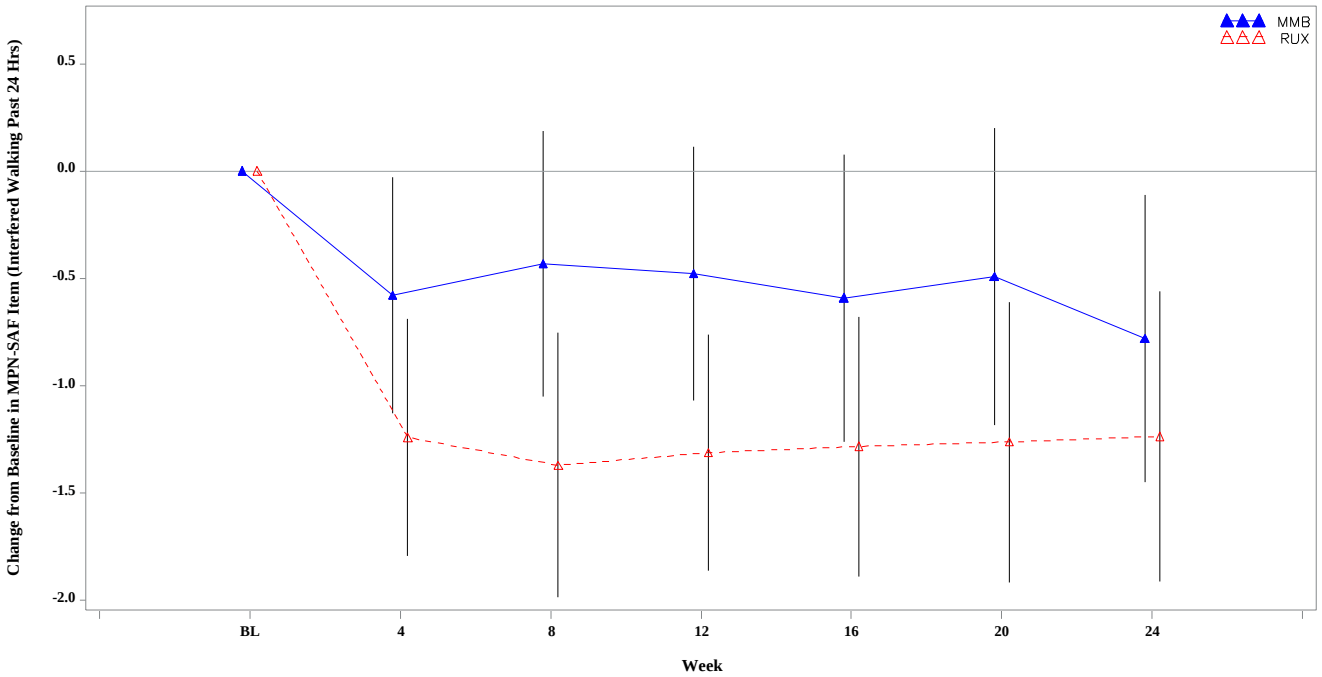
MMB	(n)	77	71	65	65	61	59	59
RUX	(n)	76	75	73	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-db.pdf 30AUG2023:12:29

Figure 2.3501: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Individual MPN-SAF Items over time
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=BFI01-Interfered Walking Past 24 Hrs



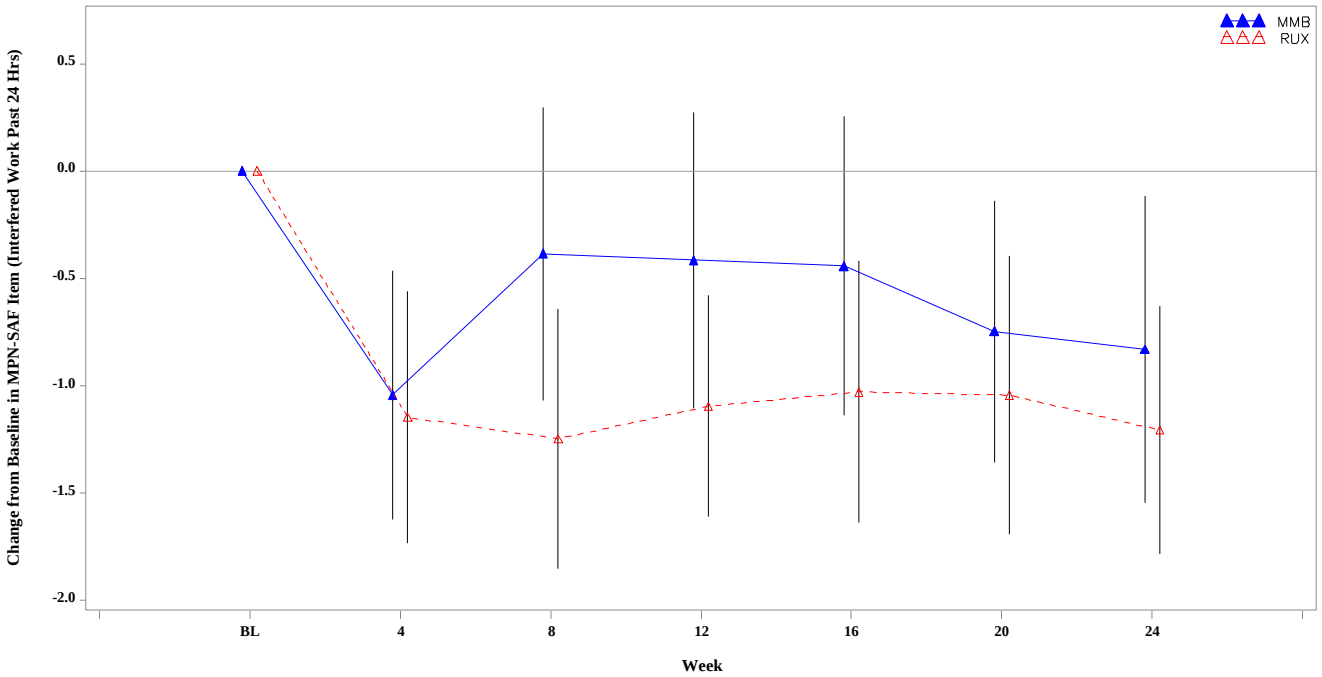
MMB	(n)	77	71	65	65	61	59	59
RUX	(n)	76	75	73	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-db.pdf 30AUG2023:12:29

Figure 2.3501: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Individual MPN-SAF Items over time
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=BFI01-Interfered Work Past 24 Hrs



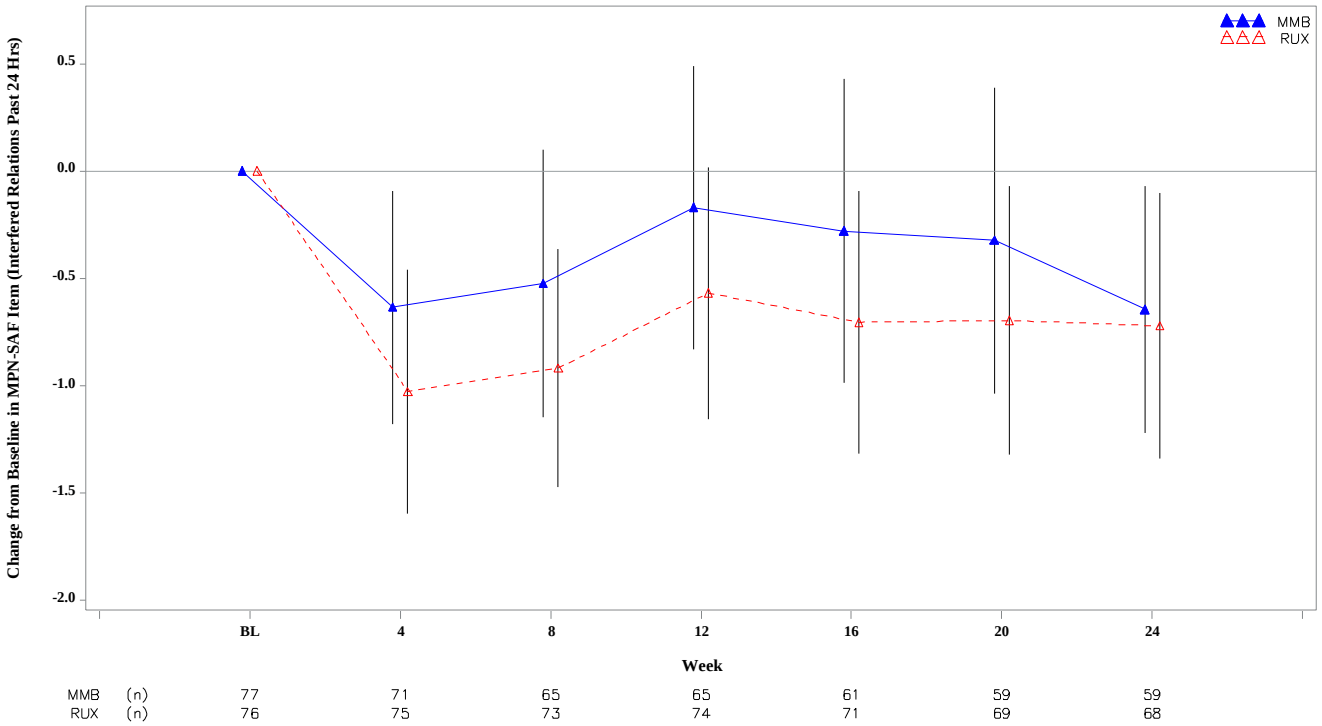
MMB	(n)	77	71	65	65	61	59	59
RUX	(n)	76	75	73	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-db.pdf 30AUG2023:12:29

Figure 2.3501: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Individual MPN-SAF Items over time
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=BFI01-Interfered Relations Past 24 Hrs



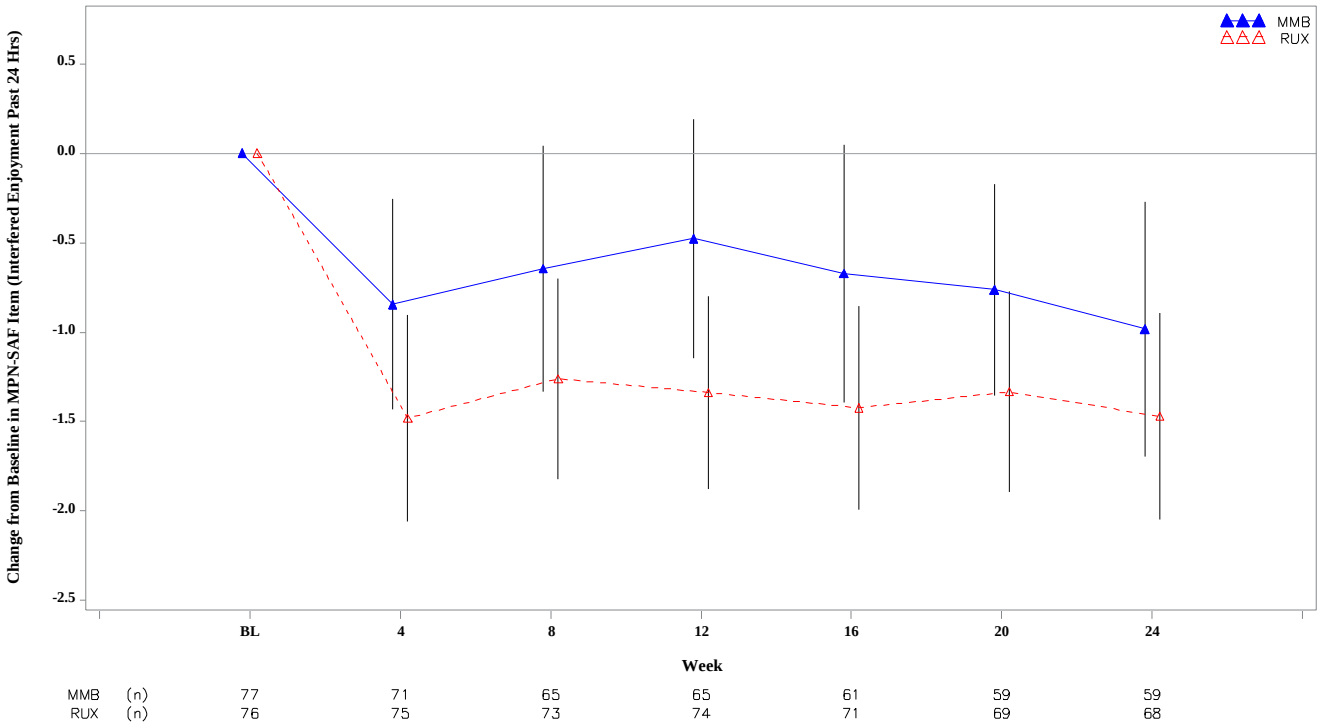
MMB	(n)	77	71	65	65	61	59	59
RUX	(n)	76	75	73	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-db.pdf 30AUG2023:12:29

Figure 2.3501: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Individual MPN-SAF Items over time
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=BFI01-Interfered Enjoyment Past 24 Hrs



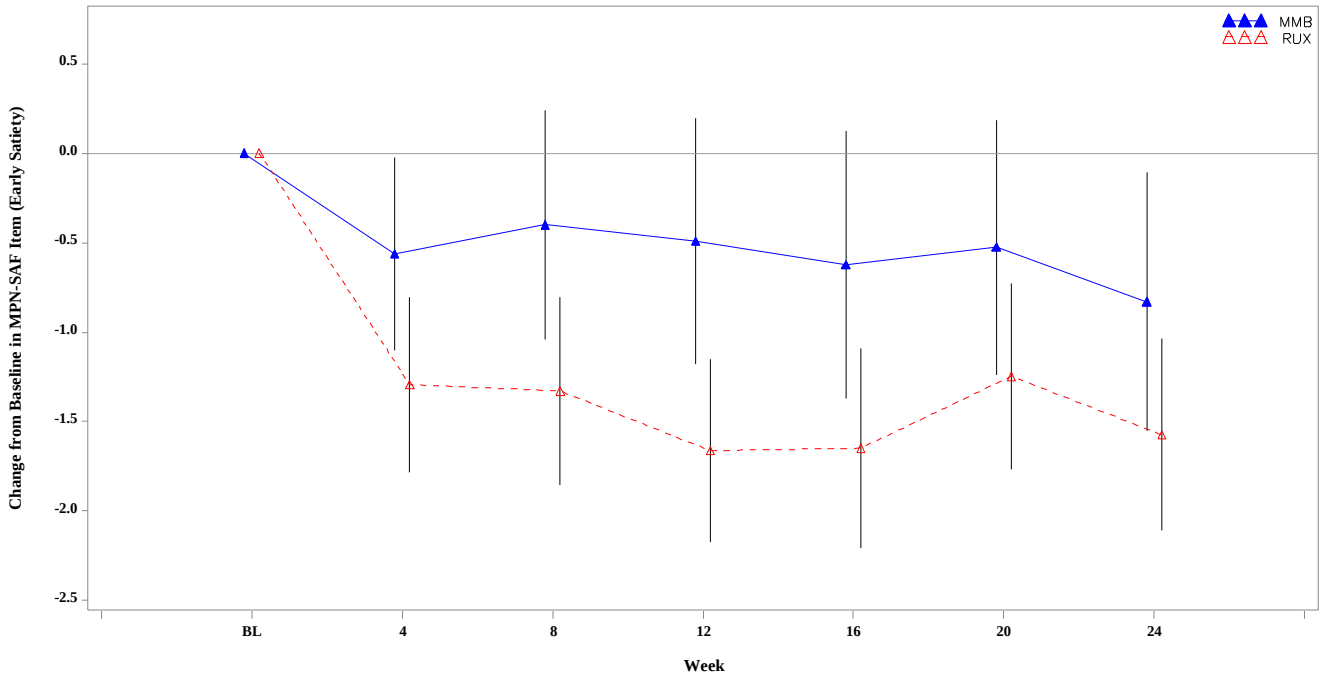
MMB	(n)	77	71	65	65	61	59	59
RUX	(n)	76	75	73	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-db.pdf 30AUG2023:12:29

Figure 2.3501: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Individual MPN-SAF Items over time
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Early Satiety



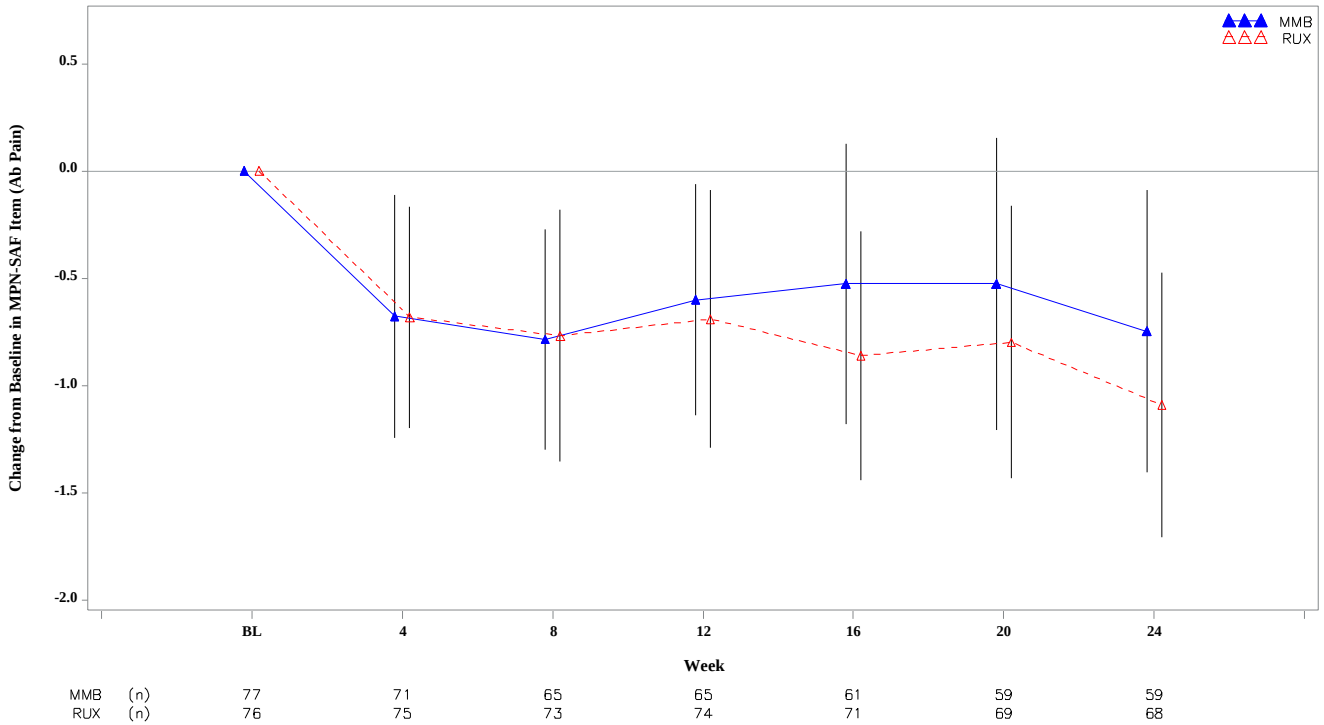
MMB	(n)	77	71	65	65	61	59	59
RUX	(n)	76	75	73	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-db.pdf 30AUG2023:12:29

Figure 2.3501: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Individual MPN-SAF Items over time
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Ab Pain



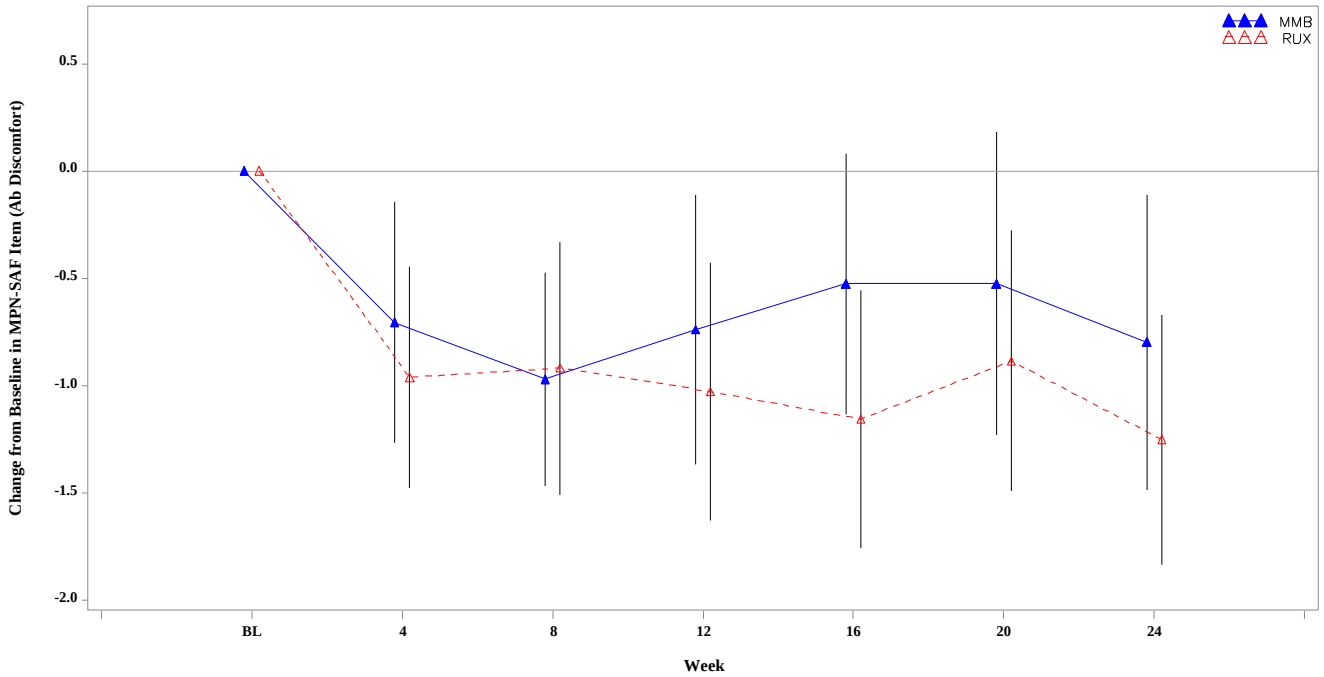
MMB	(n)	77	71	65	65	61	59	59
RUX	(n)	76	75	73	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-db.pdf 30AUG2023:12:29

Figure 2.3501: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Individual MPN-SAF Items over time
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Ab Discomfort



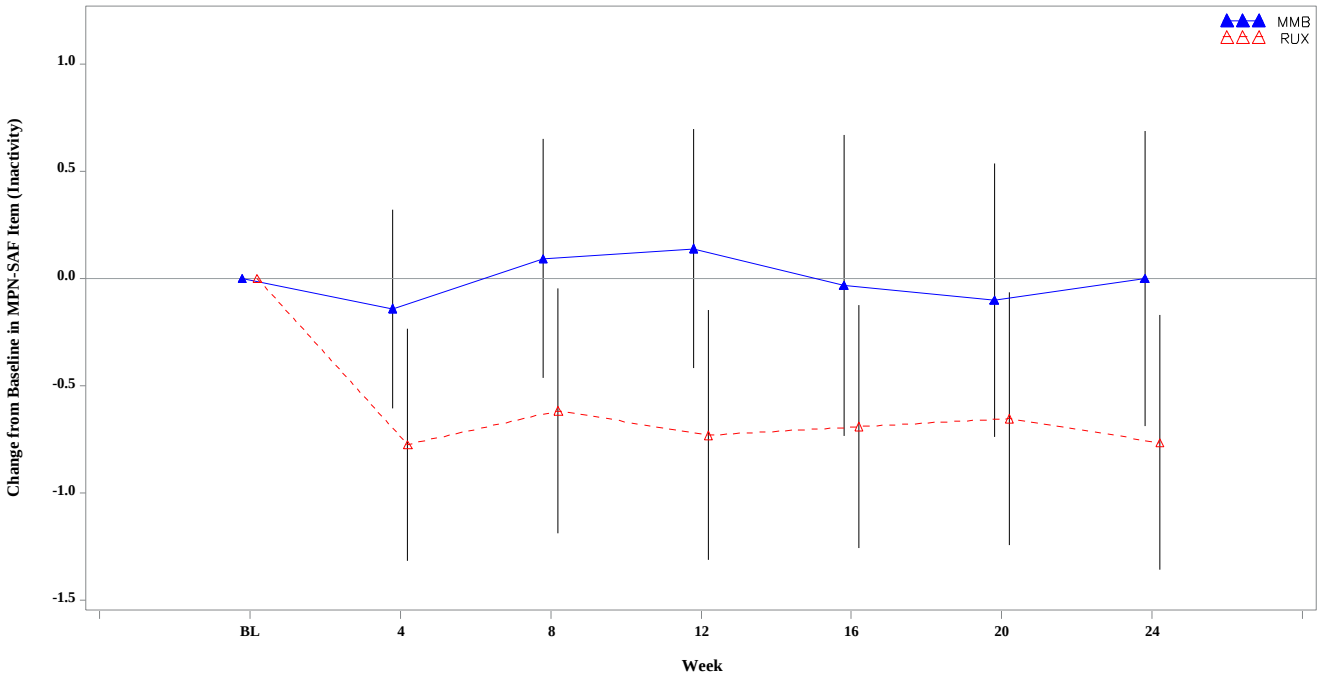
MMB	(n)	77	71	65	65	61	59	59
RUX	(n)	76	75	73	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-db.pdf 30AUG2023:12:29

Figure 2.3501: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Individual MPN-SAF Items over time
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Inactivity



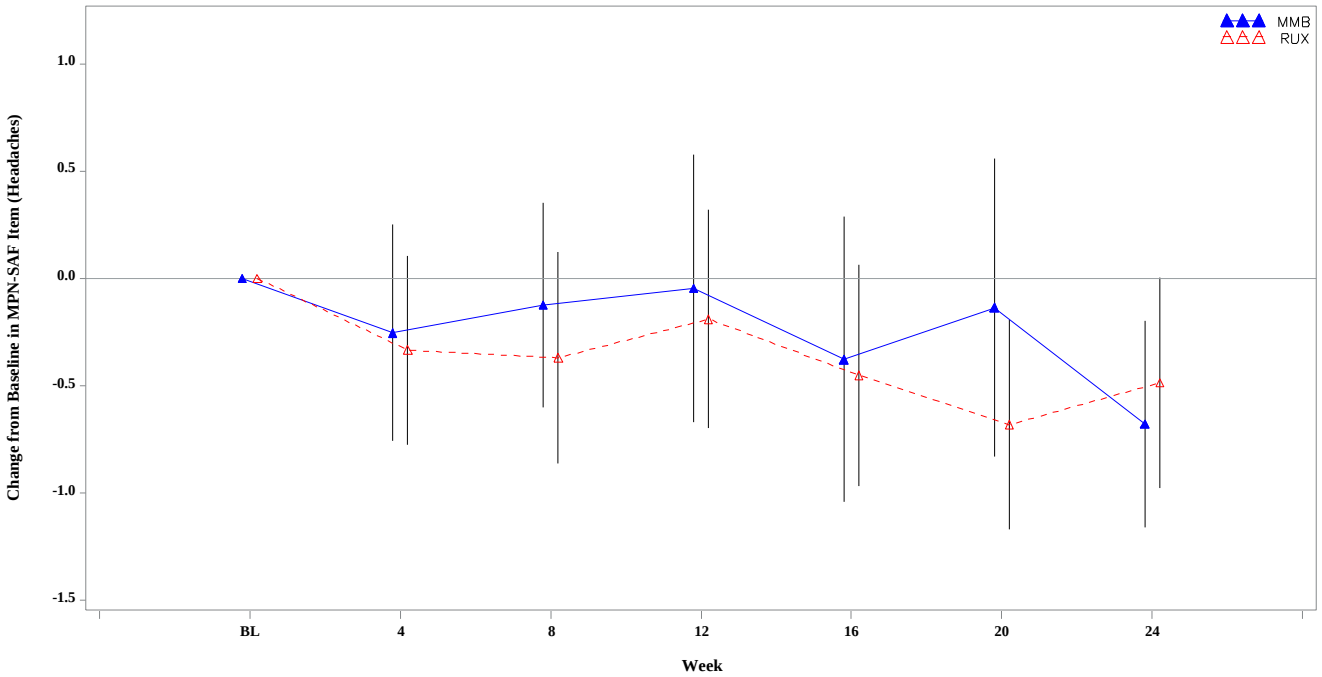
MMB	(n)	77	71	65	65	61	59	59
RUX	(n)	76	75	73	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-db.pdf 30AUG2023:12:29

Figure 2.3501: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Individual MPN-SAF Items over time
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Headaches



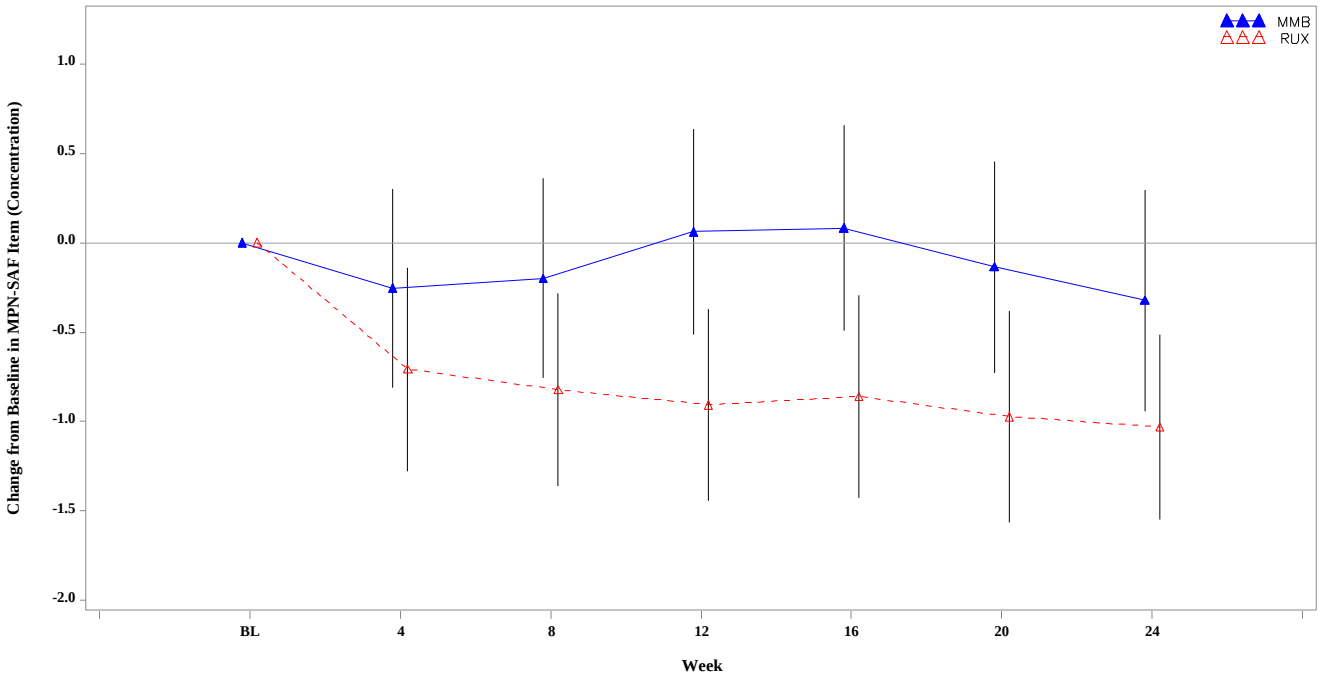
MMB	(n)	77	71	65	65	61	59	59
RUX	(n)	76	75	73	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-db.pdf 30AUG2023:12:29

Figure 2.3501: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Individual MPN-SAF Items over time
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Concentration



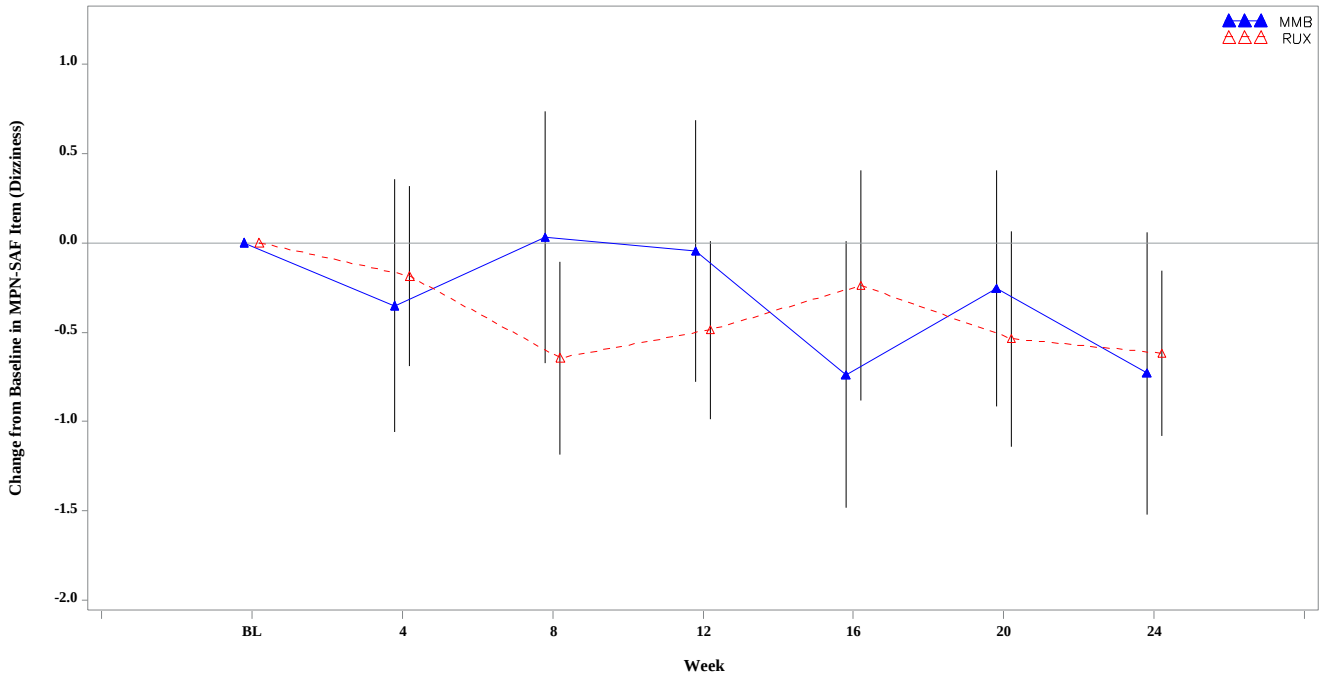
MMB	(n)	77	71	65	65	61	59	59
RUX	(n)	76	75	73	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-db.pdf 30AUG2023:12:29

Figure 2.3501: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Individual MPN-SAF Items over time
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Dizziness



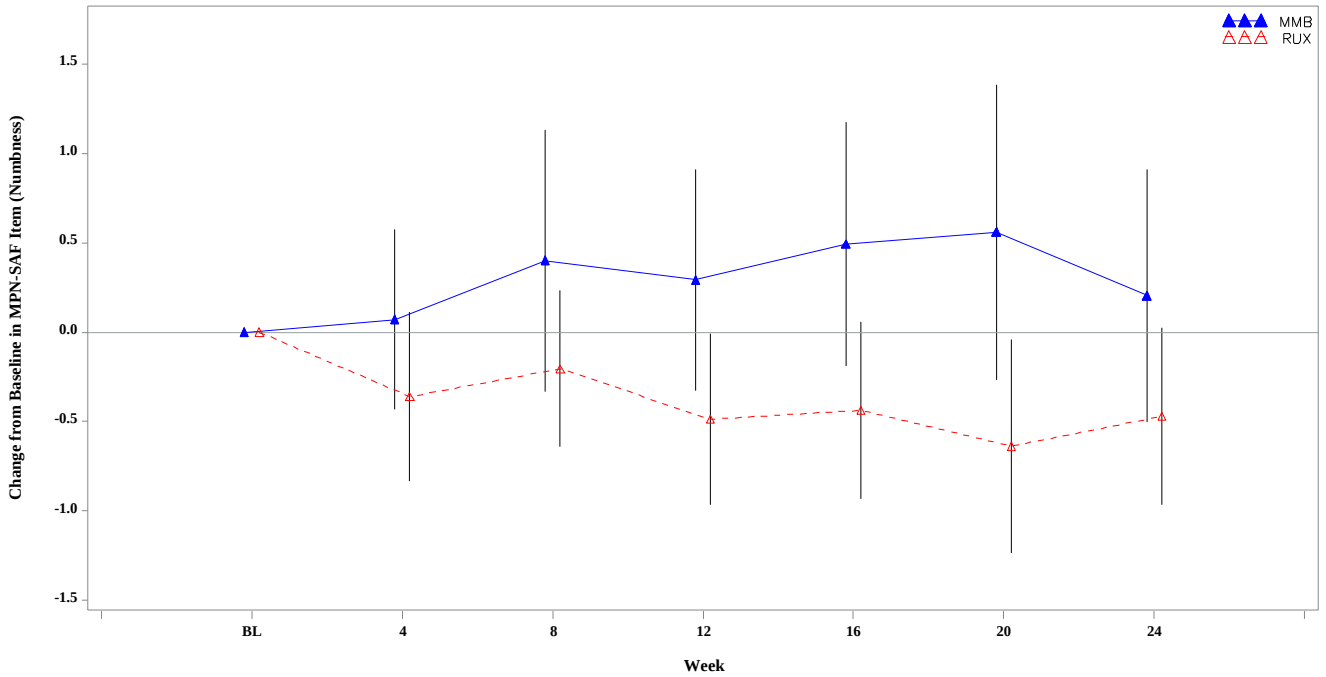
MMB	(n)	77	71	65	65	61	59	59
RUX	(n)	76	75	73	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-db.pdf 30AUG2023:12:29

Figure 2.3501: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Individual MPN-SAF Items over time
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Numbness



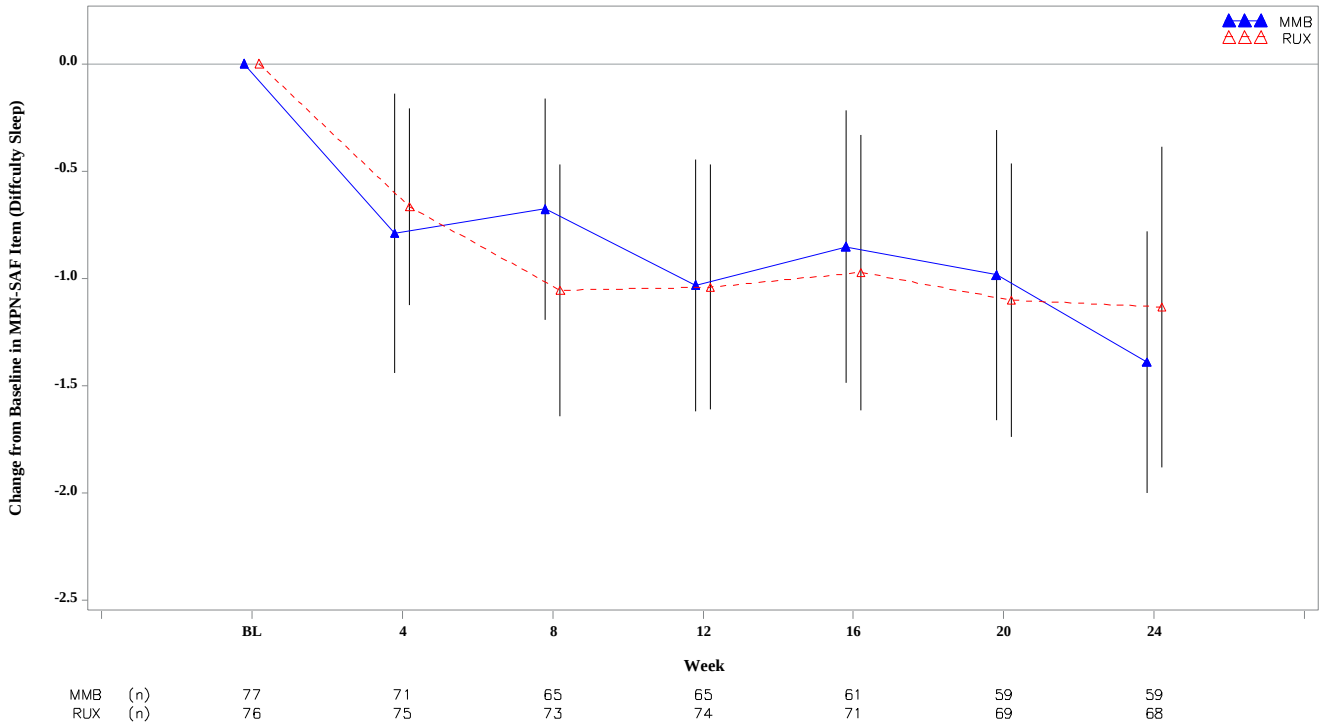
MMB	(n)	77	71	65	65	61	59	59
RUX	(n)	76	75	73	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-db.pdf 30AUG2023:12:30

Figure 2.3501: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Individual MPN-SAF Items over time
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Diffculty Sleep



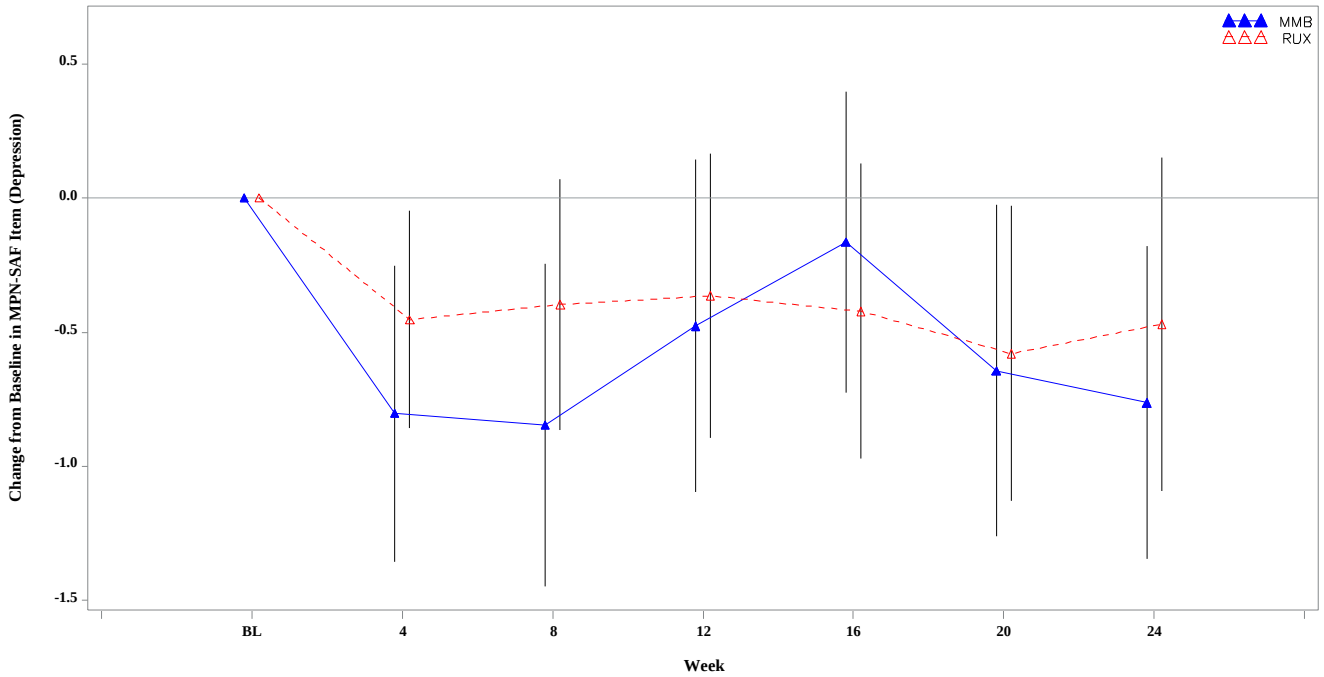
MMB	(n)	77	71	65	65	61	59	59
RUX	(n)	76	75	73	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-db.pdf 30AUG2023:12:30

Figure 2.3501: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Individual MPN-SAF Items over time
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Depression



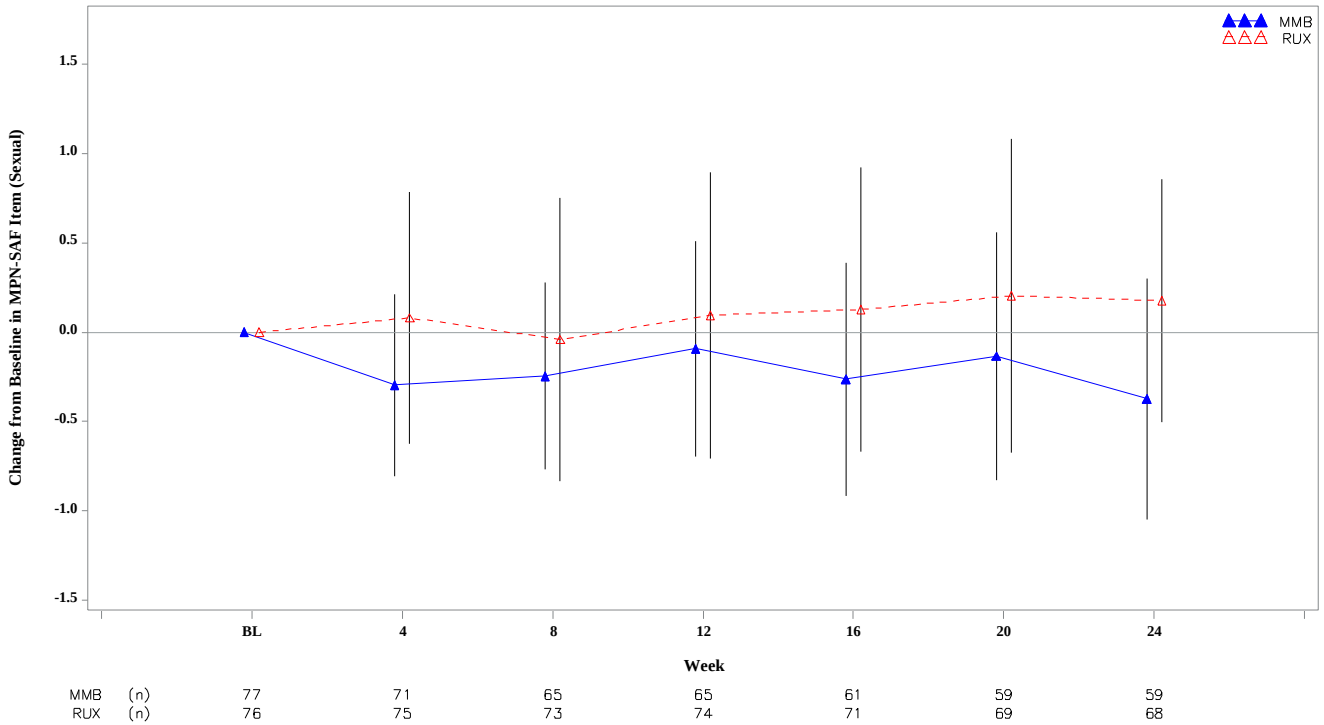
MMB	(n)	77	71	65	65	61	59	59
RUX	(n)	76	75	73	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-db.pdf 30AUG2023:12:30

Figure 2.3501: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Individual MPN-SAF Items over time
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Sexual



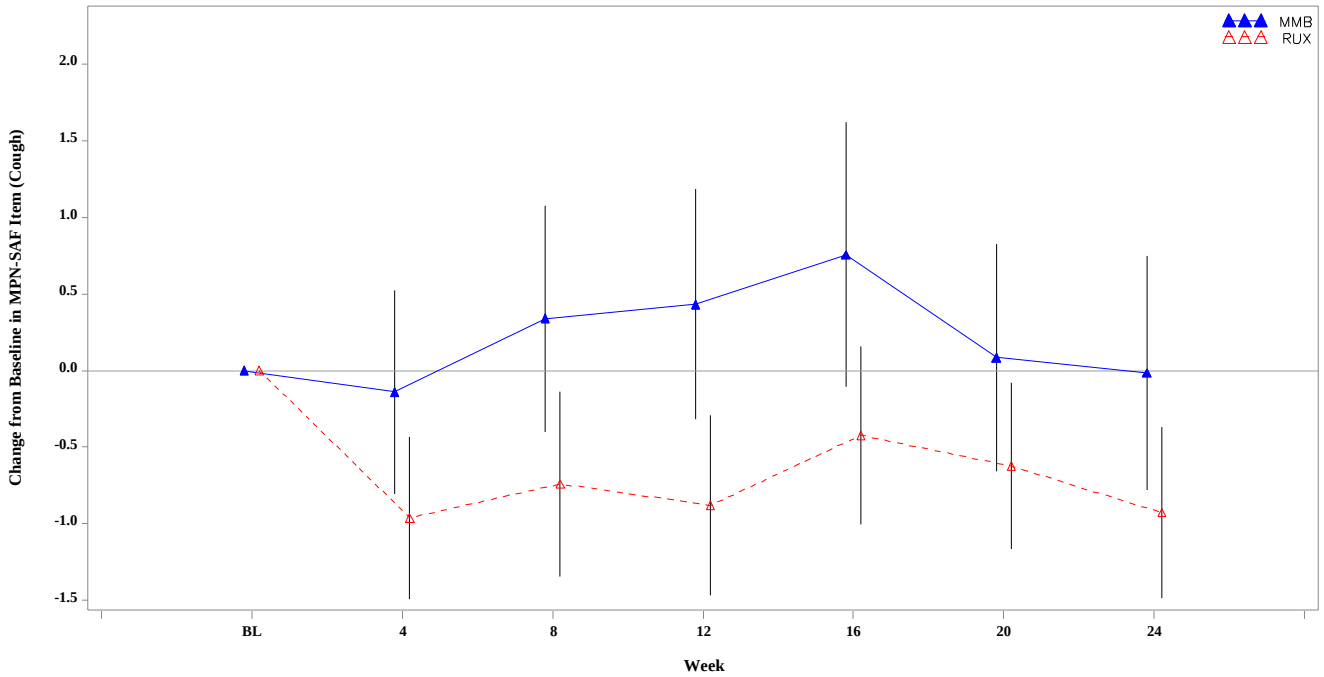
MMB	(n)	77	71	65	65	61	59	59
RUX	(n)	76	75	73	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-db.pdf 30AUG2023:12:30

Figure 2.3501: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Individual MPN-SAF Items over time
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Cough



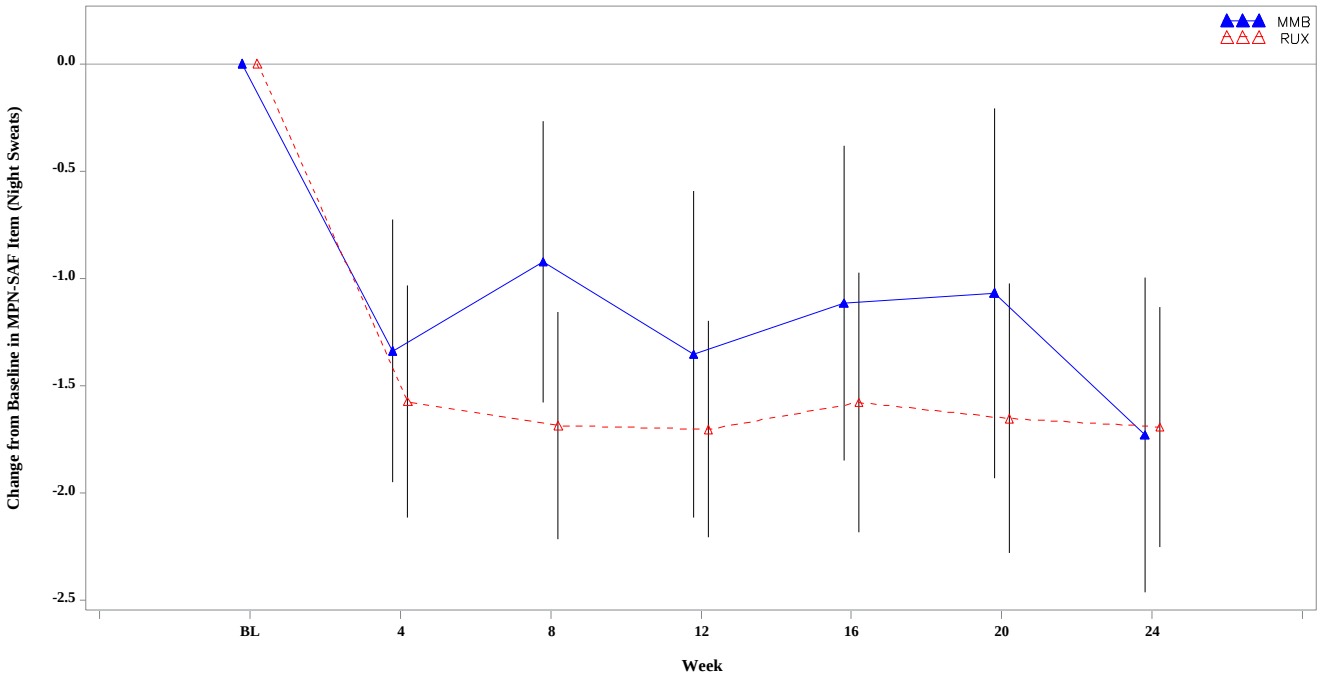
MMB	(n)	77	71	65	65	61	59	59
RUX	(n)	76	75	73	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-db.pdf 30AUG2023:12:30

Figure 2.3501: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Individual MPN-SAF Items over time
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Night Sweats



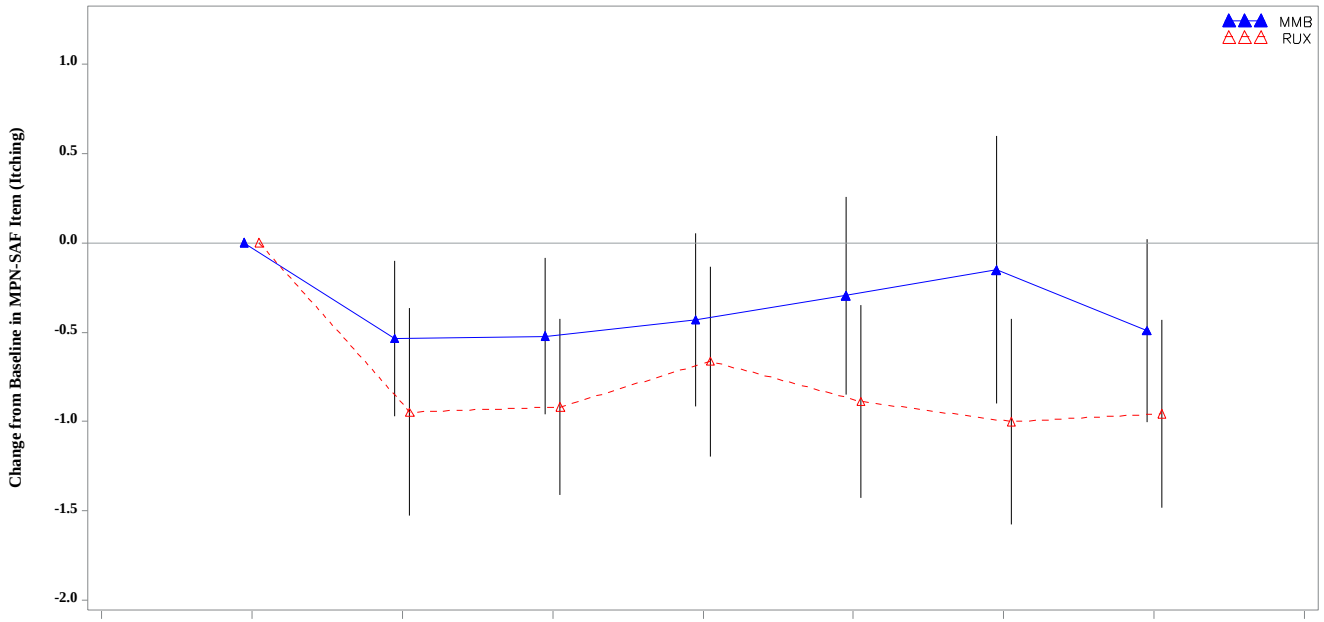
MMB	(n)	77	71	65	65	61	59	59
RUX	(n)	76	75	73	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-db.pdf 30AUG2023:12:30

Figure 2.3501: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Individual MPN-SAF Items over time
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Itching



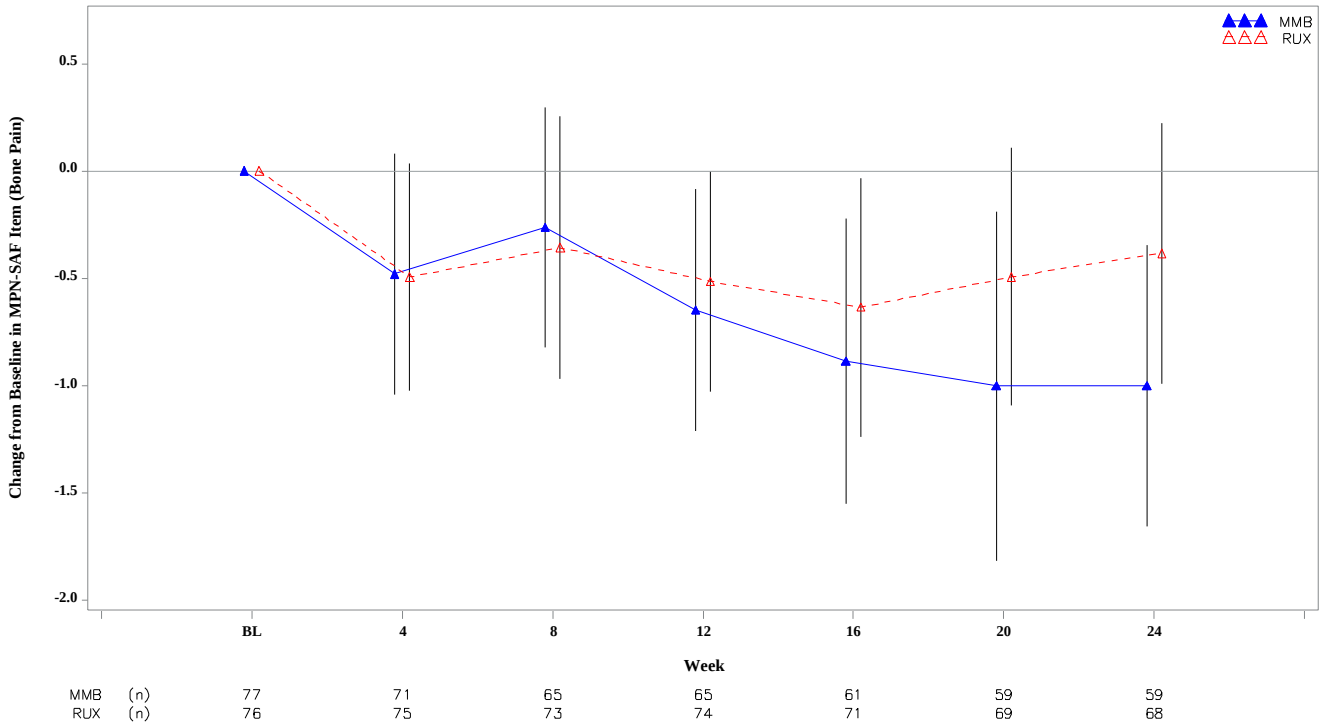
MMB	(n)	77	71	65	65	61	59	59
RUX	(n)	76	75	73	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-db.pdf 30AUG2023:12:30

Figure 2.3501: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Individual MPN-SAF Items over time
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Bone Pain



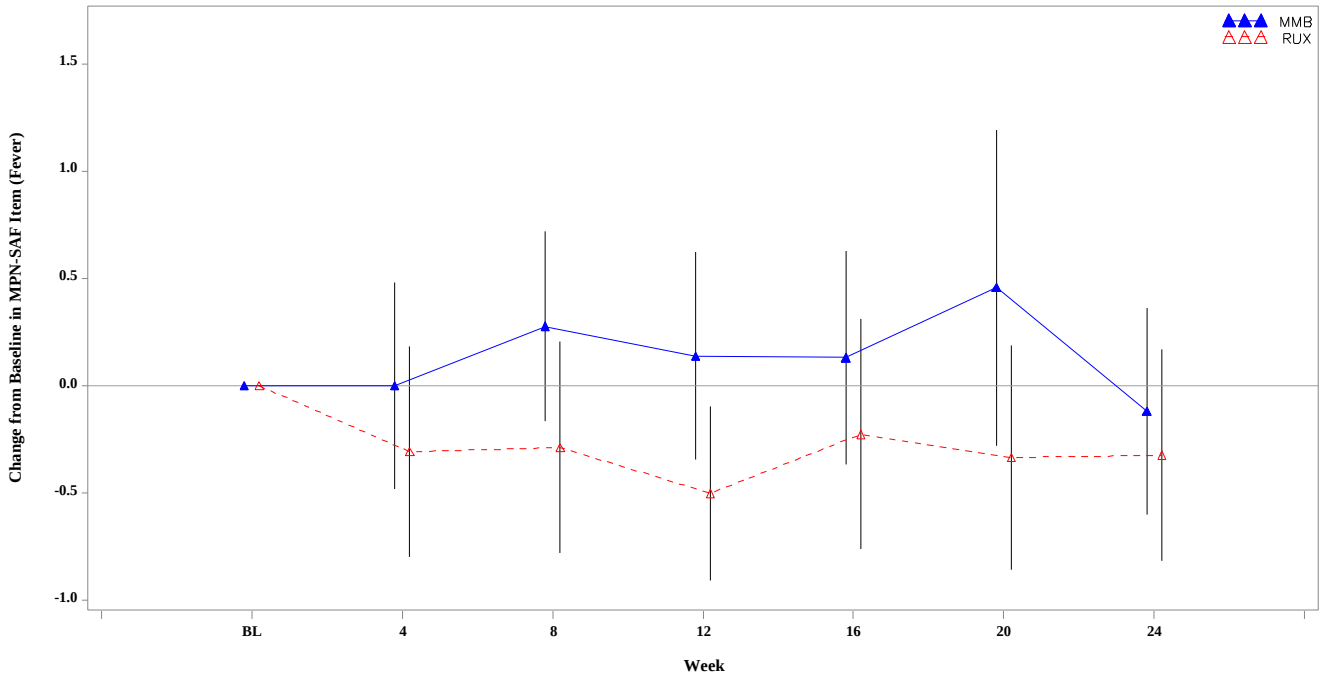
MMB	(n)	77	71	65	65	61	59	59
RUX	(n)	76	75	73	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-db.pdf 30AUG2023:12:30

Figure 2.3501: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Individual MPN-SAF Items over time
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Fever



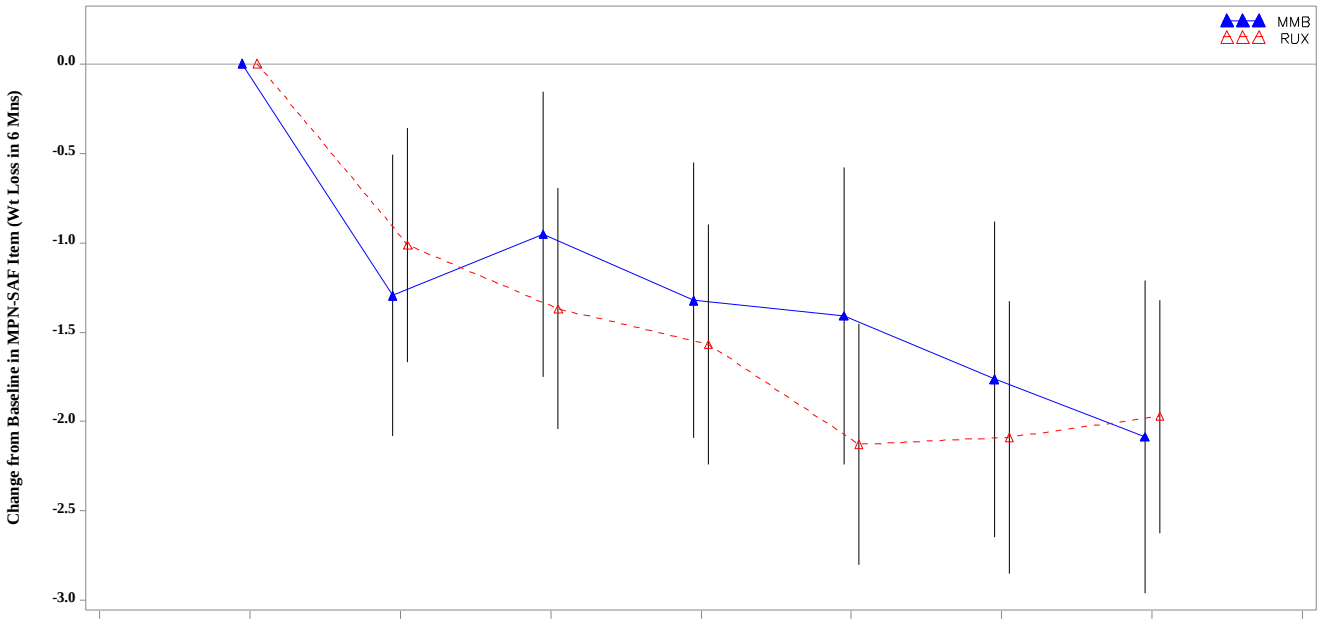
MMB	(n)	77	71	65	65	61	59	59
RUX	(n)	76	75	73	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-db.pdf 30AUG2023:12:30

Figure 2.3501: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Individual MPN-SAF Items over time
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Wt Loss in 6 Mns



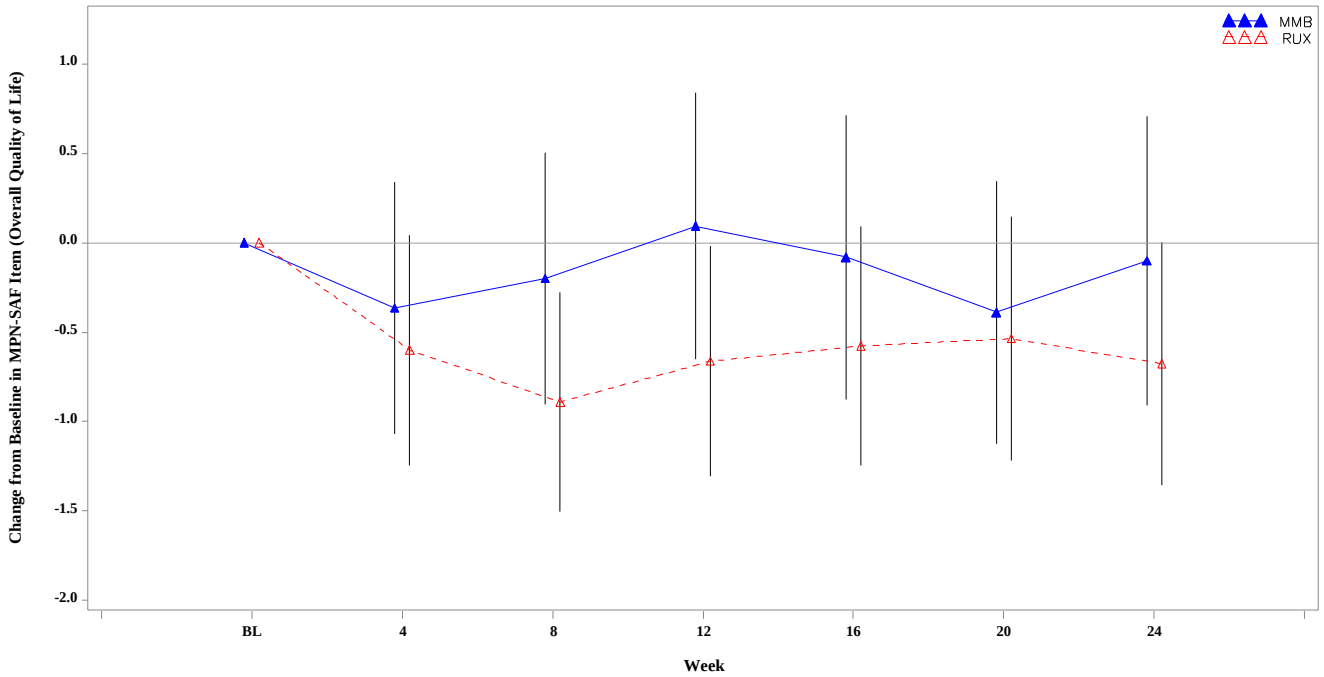
MMB	(n)	77	71	65	65	61	59	59
RUX	(n)	76	75	73	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-db.pdf 30AUG2023:12:30

Figure 2.3501: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Individual MPN-SAF Items over time
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Overall Quality of Life

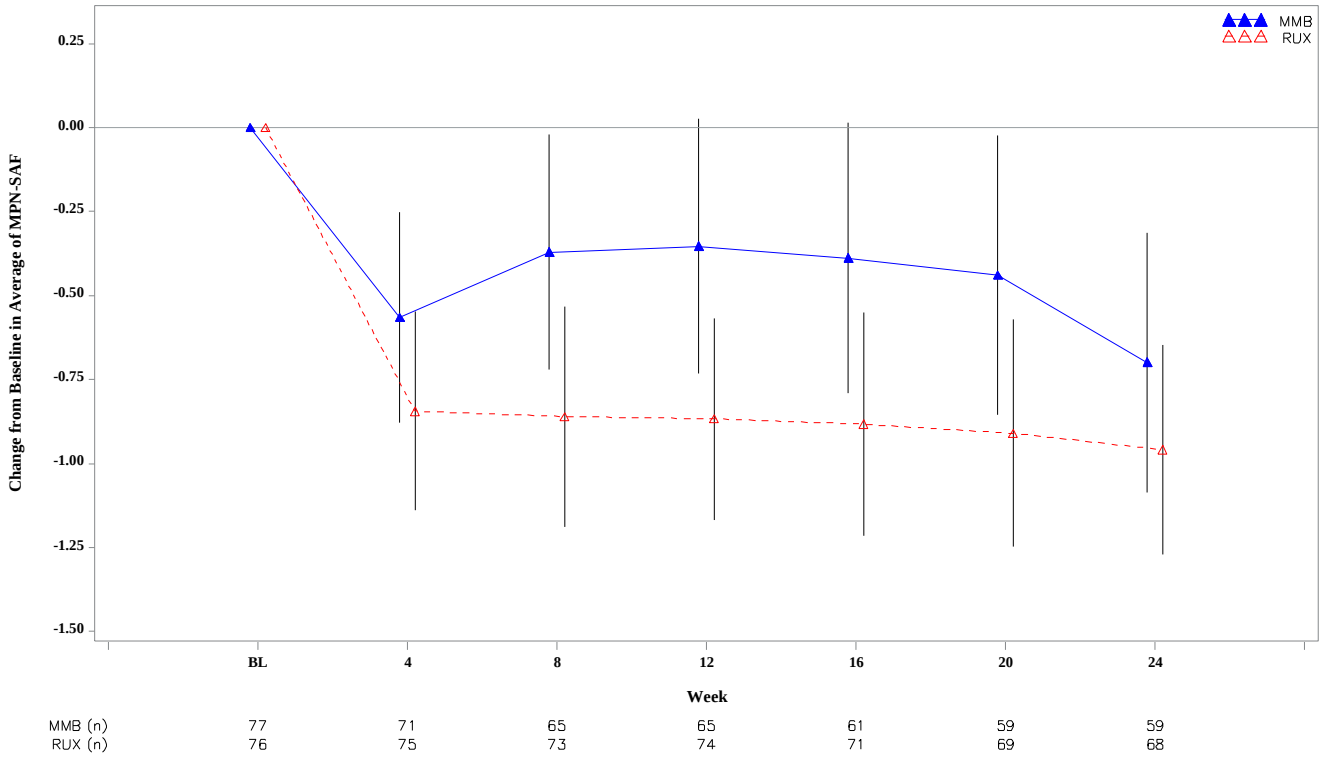


MMB	(n)	77	71	65	65	61	59	59
RUX	(n)	76	75	73	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-db.pdf 30AUG2023:12:30

Figure 2.3601: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Mean Symptom Score over time
Double-Blind Phase
ITT-Anemic Analysis Set



MMB (n)	77	71	65	65	61	59	59
RUX (n)	76	75	73	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-mpnsaf-line-chg-db.pdf 30AUG2023:12:30

GSK Oncology
Study GS-US-352-0101

Table 2.5901: Analysis of MPN-SAF Mean Questionnaire Item #1 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
MPN0101 - Early Satiety at Baseline		
n	77	76
Mean (SD)	3.0 (2.68)	3.3 (2.48)
Median	3.0	3.0
Q1, Q3	1.0, 5.0	1.0, 5.0
Min, Max	0.0, 9.0	0.0, 9.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
MPN0101 - Early Satiety at Week 4		
n	76	90
Mean (SD)	2.3 (2.52)	2.1 (2.19)
Median	2.0	2.0
Q1, Q3	0.0, 4.0	0.0, 3.0
Min, Max	0.0, 10.0	0.0, 8.0
Return Rate (%)	88%	96%
Number of Subjects in Risk	82	94
Return Rate in Risk (%)	93%	96%
Change in Early Satiety at Week 4 from Baseline		
n	71	75
Mean (SD)	-0.6 (2.27)	-1.3 (2.12)
Median	-1.0	-1.0
Q1, Q3	-1.0, 0.0	-3.0, 0.0
Min, Max	-6.0, 6.0	-7.0, 2.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn01-db.pdf 29AUG2023: 9:38

Table 2.5901: Analysis of MPN-SAF Mean Questionnaire Item #1 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	73	76	
n [2]	71	75	
MMRM: Least Squares Mean [SE] (95% CI)	-0.11 [0.25] (-0.61, 0.39)	-0.79 [0.24] (-1.27, -0.31)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.68 [0.31] (0.07, 1.29)		
MMRM: P-value	0.029		
Corrected Hedges' g (95% CI)	0.318 (-0.008, 0.645)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.099		
Percent Change in Early Satiety at Week 4 from Baseline			
n	54	60	
Mean (SD)	-3.1 (126.94)	-37.7 (56.70)	
Median	-33.3	-38.8	
Q1, Q3	-66.7, 0.0	-100.0, 0.0	
Min, Max	-100.0, 600.0	-100.0, 200.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	56	61	
n [2]	54	60	
MMRM: Least Squares Mean [SE] (95% CI)	3.19 [14.17] (-24.90, 31.28)	-32.28 [13.34] (-58.72, -5.84)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	35.47 [17.84] (0.11, 70.83)		
MMRM: P-value	0.049		
Corrected Hedges' g (95% CI)	0.340 (-0.031, 0.710)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.22		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn01-db.pdf 29AUG2023: 9:38

Table 2.5901: Analysis of MPN-SAF Mean Questionnaire Item #1 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPN0101 - Early Satiety at Week 8			
n	70	86	
Mean (SD)	2.5 (2.61)	2.0 (2.08)	
Median	2.0	2.0	
Q1, Q3	0.0, 4.0	0.0, 4.0	
Min, Max	0.0, 10.0	0.0, 8.0	
Return Rate (%)	81%	91%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	91%	
Change in Early Satiety at Week 8 from Baseline			
n	65	73	
Mean (SD)	-0.4 (2.58)	-1.3 (2.25)	
Median	-1.0	-1.0	
Q1, Q3	-2.0, 0.0	-3.0, 0.0	
Min, Max	-6.0, 7.0	-7.0, 4.0	
Difference in Change from Baseline at Week 8			
n [1]	73	76	
n [2]	65	73	
MMRM: Least Squares Mean [SE] (95% CI)	0.12 [0.27] (-0.42, 0.66)	-0.94 [0.26] (-1.45, -0.43)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.06 [0.34] (0.40, 1.72)		
MMRM: P-value	0.002		
Corrected Hedges' g (95% CI)	0.478 (0.139, 0.817)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.098		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5901: Analysis of MPN-SAF Mean Questionnaire Item #1 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Early Satiety at Week 8 from Baseline		
n	50	58
Mean (SD)	-8.9 (121.50)	-38.6 (59.99)
Median	-33.3	-50.0
Q1, Q3	-66.7, 0.0	-100.0, 0.0
Min, Max	-100.0, 600.0	-100.0, 133.3
Difference in Percent Change from Baseline at Week 8		
n [1]	56	61
n [2]	50	58
MMRM: Least Squares Mean [SE] (95% CI)	3.24 [14.25] (-24.99, 31.48)	-35.08 [13.30] (-61.43, -8.72)
MMRM: Least Squares Mean Difference [SE] (95% CI)	38.32 [17.87] (2.91, 73.73)	
MMRM: P-value	0.034	
Corrected Hedges' g (95% CI)	0.377 (-0.005, 0.758)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.18	
MPN0101 - Early Satiety at Week 12		
n	71	89
Mean (SD)	2.3 (2.40)	1.6 (1.79)
Median	2.0	1.0
Q1, Q3	0.0, 4.0	0.0, 2.0
Min, Max	0.0, 10.0	0.0, 8.0
Return Rate (%)	83%	95%
Number of Subjects in Risk	76	94
Return Rate in Risk (%)	93%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5901: Analysis of MPN-SAF Mean Questionnaire Item #1 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Change in Early Satiety at Week 12 from Baseline		
n	65	74
Mean (SD)	-0.5 (2.77)	-1.7 (2.21)
Median	-1.0	-1.0
Q1, Q3	-2.0, 0.0	-3.0, 0.0
Min, Max	-6.0, 7.0	-7.0, 2.0
Difference in Change from Baseline at Week 12		
n [1]	73	76
n [2]	65	74
MMRM: Least Squares Mean [SE] (95% CI)	-0.05 [0.26] (-0.56, 0.46)	-1.17 [0.24] (-1.65, -0.69)
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.12 [0.31] (0.51, 1.73)	
MMRM: P-value	< 0.001	
Corrected Hedges' g (95% CI)	0.537 (0.198, 0.876)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.008	
Percent Change in Early Satiety at Week 12 from Baseline		
n	49	59
Mean (SD)	-10.3 (118.41)	-49.3 (50.47)
Median	-37.5	-50.0
Q1, Q3	-100.0, 0.0	-100.0, -20.0
Min, Max	-100.0, 500.0	-100.0, 100.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5901: Analysis of MPN-SAF Mean Questionnaire Item #1 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	56	61	
n [2]	49	59	
MMRM: Least Squares Mean [SE] (95% CI)	-4.90 [12.86] (-30.38, 20.58)		-44.05 [11.90] (-67.64, -20.45)
MMRM: Least Squares Mean Difference [SE] (95% CI)	39.15 [15.71] (8.02, 70.27)		
MMRM: P-value	0.014		
Corrected Hedges' g (95% CI)	0.428 (0.045, 0.811)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.049		
MPN0101 - Early Satiety at Week 16			
n	67	83	
Mean (SD)	2.2 (2.70)	1.6 (2.09)	
Median	1.0	1.0	
Q1, Q3	0.0, 4.0	0.0, 2.0	
Min, Max	0.0, 10.0	0.0, 9.0	
Return Rate (%)	78%	88%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	89%	91%	
Change in Early Satiety at Week 16 from Baseline			
n	61	71	
Mean (SD)	-0.6 (2.92)	-1.6 (2.36)	
Median	-1.0	-1.0	
Q1, Q3	-1.0, 0.0	-3.0, 0.0	
Min, Max	-8.0, 6.0	-7.0, 5.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5901: Analysis of MPN-SAF Mean Questionnaire Item #1 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	73	76	
n [2]	61	71	
MMRM: Least Squares Mean [SE] (95% CI)	-0.15 [0.29] (-0.72, 0.42)	-1.18 [0.27] (-1.72, -0.64)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.03 [0.36] (0.32, 1.74)		
MMRM: P-value	0.005		
Corrected Hedges' g (95% CI)	0.449 (0.103, 0.796)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.030		
Percent Change in Early Satiety at Week 16 from Baseline			
n	47	56	
Mean (SD)	-16.8 (113.15)	-50.1 (59.58)	
Median	-40.0	-69.0	
Q1, Q3	-100.0, 0.0	-100.0, -10.0	
Min, Max	-100.0, 500.0	-100.0, 200.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	56	61	
n [2]	47	56	
MMRM: Least Squares Mean [SE] (95% CI)	-13.76 [13.03] (-39.58, 12.07)	-44.63 [12.10] (-68.62, -20.65)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	30.88 [16.00] (-0.82, 62.58)		
MMRM: P-value	0.056		
Corrected Hedges' g (95% CI)	0.341 (-0.050, 0.731)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.10		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5901: Analysis of MPN-SAF Mean Questionnaire Item #1 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPN0101 - Early Satiety at Week 20			
n	64	83	
Mean (SD)	2.3 (2.84)	2.0 (2.10)	
Median	1.0	2.0	
Q1, Q3	0.0, 3.0	0.0, 3.0	
Min, Max	0.0, 10.0	0.0, 9.0	
Return Rate (%)	74%	88%	
Number of Subjects in Risk	74	90	
Return Rate in Risk (%)	86%	92%	
Change in Early Satiety at Week 20 from Baseline			
n	59	69	
Mean (SD)	-0.5 (2.73)	-1.2 (2.16)	
Median	0.0	-1.0	
Q1, Q3	-2.0, 0.0	-3.0, 0.0	
Min, Max	-8.0, 7.0	-6.0, 4.0	
Difference in Change from Baseline at Week 20			
n [1]	73	76	
n [2]	59	69	
MMRM: Least Squares Mean [SE] (95% CI)	-0.07 [0.29] (-0.63, 0.50)	-0.81 [0.27] (-1.34, -0.27)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.74 [0.35] (0.04, 1.44)		
MMRM: P-value	0.038		
Corrected Hedges' g (95% CI)	0.332 (-0.018, 0.682)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.087		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5901: Analysis of MPN-SAF Mean Questionnaire Item #1 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Early Satiety at Week 20 from Baseline		
n	45	55
Mean (SD)	-5.0 (133.59)	-38.9 (51.84)
Median	-33.3	-50.0
Q1, Q3	-85.7, 16.7	-85.7, 0.0
Min, Max	-100.0, 700.0	-100.0, 100.0
Difference in Percent Change from Baseline at Week 20		
n [1]	56	61
n [2]	45	55
MMRM: Least Squares Mean [SE] (95% CI)	-3.32 [13.96] (-30.98, 24.34)	-34.25 [12.98] (-59.99, -8.52)
MMRM: Least Squares Mean Difference [SE] (95% CI)	30.94 [17.40] (-3.55, 65.42)	
MMRM: P-value	0.078	
Corrected Hedges' g (95% CI)	0.323 (-0.074, 0.719)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.30	
MPN0101 - Early Satiety at Week 24		
n	65	82
Mean (SD)	2.0 (2.35)	1.5 (1.94)
Median	1.0	1.0
Q1, Q3	0.0, 3.0	0.0, 2.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	76%	87%
Number of Subjects in Risk	70	87
Return Rate in Risk (%)	93%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5901: Analysis of MPN-SAF Mean Questionnaire Item #1 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Change in Early Satiety at Week 24 from Baseline		
n	59	68
Mean (SD)	-0.8 (2.77)	-1.6 (2.21)
Median	-1.0	-1.0
Q1, Q3	-2.0, 0.0	-3.0, 0.0
Min, Max	-8.0, 5.0	-7.0, 3.0
Difference in Change from Baseline at Week 24		
n [1]	73	76
n [2]	59	68
MMRM: Least Squares Mean [SE] (95% CI)	-0.15 [0.27] (-0.69, 0.40)	-1.10 [0.26] (-1.61, -0.58)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.95 [0.34] (0.28, 1.62)	
MMRM: P-value	0.005	
Corrected Hedges' g (95% CI)	0.445 (0.092, 0.798)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.10	
Percent Change in Early Satiety at Week 24 from Baseline		
n	45	53
Mean (SD)	-23.6 (101.08)	-51.9 (50.01)
Median	-50.0	-66.7
Q1, Q3	-100.0, 0.0	-100.0, 0.0
Min, Max	-100.0, 400.0	-100.0, 100.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5901: Analysis of MPN-SAF Mean Questionnaire Item #1 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	56	61	
n [2]	45	53	
MMRM: Least Squares Mean [SE] (95% CI)	-5.64 [14.07] (-33.52, 22.25)		-43.98 [13.06] (-69.86, -18.09)
MMRM: Least Squares Mean Difference [SE] (95% CI)	38.34 [17.55] (3.55, 73.13)		
MMRM: P-value	0.031		
Corrected Hedges' g (95% CI)	0.401 (0.000, 0.803)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.29		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.5902: Analysis of MPN-SAF Mean Questionnaire Item #2 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
MPN0102 - Abdominal Pain at Baseline		
n	77	76
Mean (SD)	2.5 (2.89)	2.4 (2.81)
Median	2.0	2.0
Q1, Q3	0.0, 4.0	0.0, 3.5
Min, Max	0.0, 10.0	0.0, 9.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
MPN0102 - Abdominal Pain at Week 4		
n	76	90
Mean (SD)	1.8 (2.29)	1.8 (2.07)
Median	1.0	1.0
Q1, Q3	0.0, 3.0	0.0, 3.0
Min, Max	0.0, 10.0	0.0, 9.0
Return Rate (%)	88%	96%
Number of Subjects in Risk	82	94
Return Rate in Risk (%)	93%	96%
Change in Abdominal Pain at Week 4 from Baseline		
n	71	75
Mean (SD)	-0.7 (2.38)	-0.7 (2.24)
Median	0.0	0.0
Q1, Q3	-1.0, 0.0	-2.0, 1.0
Min, Max	-8.0, 7.0	-9.0, 3.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5902: Analysis of MPN-SAF Mean Questionnaire Item #2 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	73	76	
n [2]	71	75	
MMRM: Least Squares Mean [SE] (95% CI)	-0.35 [0.24] (-0.82, 0.12)	-0.43 [0.23] (-0.88, 0.01)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.09 [0.29] (-0.49, 0.66)		
MMRM: P-value	0.77		
Corrected Hedges' g (95% CI)	0.043 (-0.282, 0.367)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.85		
Percent Change in Abdominal Pain at Week 4 from Baseline			
n	44	47	
Mean (SD)	-18.5 (77.26)	-21.4 (74.88)	
Median	-33.3	-33.3	
Q1, Q3	-72.5, 0.0	-85.7, 0.0	
Min, Max	-100.0, 233.3	-100.0, 200.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	46	47	
n [2]	44	47	
MMRM: Least Squares Mean [SE] (95% CI)	-13.58 [11.90] (-37.24, 10.08)	-17.61 [11.40] (-40.28, 5.06)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	4.03 [15.01] (-25.82, 33.87)		
MMRM: P-value	0.79		
Corrected Hedges' g (95% CI)	0.051 (-0.360, 0.462)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.93		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5902: Analysis of MPN-SAF Mean Questionnaire Item #2 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPN0102 - Abdominal Pain at Week 8			
n	70	86	
Mean (SD)	1.9 (2.40)	1.6 (1.91)	
Median	1.0	1.0	
Q1, Q3	0.0, 3.0	0.0, 3.0	
Min, Max	0.0, 10.0	0.0, 8.0	
Return Rate (%)	81%	91%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	91%	
Change in Abdominal Pain at Week 8 from Baseline			
n	65	73	
Mean (SD)	-0.8 (2.07)	-0.8 (2.51)	
Median	0.0	0.0	
Q1, Q3	-2.0, 0.0	-2.0, 1.0	
Min, Max	-6.0, 4.0	-9.0, 5.0	
Difference in Change from Baseline at Week 8			
n [1]	73	76	
n [2]	65	73	
MMRM: Least Squares Mean [SE] (95% CI)		-0.21 [0.25] (-0.70, 0.27)	-0.56 [0.23] (-1.01, -0.10)
MMRM: Least Squares Mean Difference [SE] (95% CI)		0.35 [0.30] (-0.25, 0.94)	
MMRM: P-value		0.25	
Corrected Hedges' g (95% CI)		0.175 (-0.160, 0.510)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value		0.47	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5902: Analysis of MPN-SAF Mean Questionnaire Item #2 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Abdominal Pain at Week 8 from Baseline			
n	40	45	
Mean (SD)	-35.0 (50.34)	-26.9 (69.96)	
Median	-33.3	-50.0	
Q1, Q3	-73.3, 0.0	-80.0, 0.0	
Min, Max	-100.0, 100.0	-100.0, 166.7	
Difference in Percent Change from Baseline at Week 8			
n [1]	46	47	
n [2]	40	45	
MMRM: Least Squares Mean [SE] (95% CI)	-18.93 [11.57] (-41.94, 4.08)	-25.61 [10.92] (-47.33, -3.90)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	6.68 [14.39] (-21.92, 35.28)		
MMRM: P-value	0.64		
Corrected Hedges' g (95% CI)	0.090 (-0.336, 0.517)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.98		
MPN0102 - Abdominal Pain at Week 12			
n	71	89	
Mean (SD)	2.0 (2.29)	1.8 (1.82)	
Median	1.0	1.0	
Q1, Q3	0.0, 3.0	0.0, 3.0	
Min, Max	0.0, 10.0	0.0, 8.0	
Return Rate (%)	83%	95%	
Number of Subjects in Risk	76	94	
Return Rate in Risk (%)	93%	95%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn02-db.pdf 29AUG2023: 9:38

Table 2.5902: Analysis of MPN-SAF Mean Questionnaire Item #2 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Abdominal Pain at Week 12 from Baseline			
n	65	74	
Mean (SD)	-0.6 (2.17)	-0.7 (2.59)	
Median	0.0	0.0	
Q1, Q3	-2.0, 0.0	-2.0, 1.0	
Min, Max	-7.0, 4.0	-9.0, 6.0	
Difference in Change from Baseline at Week 12			
n [1]	73	76	
n [2]	65	74	
MMRM: Least Squares Mean [SE] (95% CI)	-0.17 [0.25] (-0.65, 0.32)	-0.48 [0.23] (-0.94, -0.03)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.32 [0.30] (-0.27, 0.91)		
MMRM: P-value	0.29		
Corrected Hedges' g (95% CI)	0.159 (-0.175, 0.493)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.97		
Percent Change in Abdominal Pain at Week 12 from Baseline			
n	41	46	
Mean (SD)	-27.9 (65.84)	-31.9 (82.56)	
Median	-33.3	-63.3	
Q1, Q3	-83.3, 0.0	-100.0, 0.0	
Min, Max	-100.0, 200.0	-100.0, 300.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn02-db.pdf 29AUG2023: 9:38

Table 2.5902: Analysis of MPN-SAF Mean Questionnaire Item #2 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	46	47	
n [2]	41	46	
MMRM: Least Squares Mean [SE] (95% CI)	-18.21 [12.43] (-42.92, 6.50)	-28.52 [11.73] (-51.84, -5.21)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	10.32 [15.68] (-20.85, 41.48)		
MMRM: P-value	0.51		
Corrected Hedges' g (95% CI)	0.129 (-0.293, 0.550)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.33		
MPN0102 - Abdominal Pain at Week 16			
n	67	83	
Mean (SD)	2.1 (2.61)	1.6 (2.02)	
Median	1.0	1.0	
Q1, Q3	0.0, 3.0	0.0, 3.0	
Min, Max	0.0, 10.0	0.0, 8.0	
Return Rate (%)	78%	88%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	89%	91%	
Change in Abdominal Pain at Week 16 from Baseline			
n	61	71	
Mean (SD)	-0.5 (2.55)	-0.9 (2.45)	
Median	0.0	0.0	
Q1, Q3	-2.0, 1.0	-2.0, 0.0	
Min, Max	-8.0, 7.0	-9.0, 4.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn02-db.pdf 29AUG2023: 9:38

Table 2.5902: Analysis of MPN-SAF Mean Questionnaire Item #2 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	73	76	
n [2]	61	71	
MMRM: Least Squares Mean [SE] (95% CI)	0.05 [0.27] (-0.49, 0.59)	-0.61 [0.25] (-1.12, -0.11)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.67 [0.34] (-0.01, 1.34)		
MMRM: P-value	0.053		
Corrected Hedges' g (95% CI)	0.309 (-0.035, 0.653)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.57		
Percent Change in Abdominal Pain at Week 16 from Baseline			
n	39	44	
Mean (SD)	-16.5 (80.88)	-30.9 (72.15)	
Median	-30.0	-47.2	
Q1, Q3	-88.9, 25.0	-100.0, 0.0	
Min, Max	-100.0, 300.0	-100.0, 150.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	46	47	
n [2]	39	44	
MMRM: Least Squares Mean [SE] (95% CI)	-3.42 [12.78] (-28.83, 21.99)	-29.41 [12.09] (-53.43, -5.38)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	25.99 [16.22] (-6.27, 58.24)		
MMRM: P-value	0.11		
Corrected Hedges' g (95% CI)	0.322 (-0.112, 0.756)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.18		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5902: Analysis of MPN-SAF Mean Questionnaire Item #2 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPN0102 - Abdominal Pain at Week 20			
n	64	83	
Mean (SD)	2.1 (2.67)	1.7 (2.00)	
Median	1.0	1.0	
Q1, Q3	0.0, 3.5	0.0, 3.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	74%	88%	
Number of Subjects in Risk	74	90	
Return Rate in Risk (%)	86%	92%	
Change in Abdominal Pain at Week 20 from Baseline			
n	59	69	
Mean (SD)	-0.5 (2.61)	-0.8 (2.64)	
Median	0.0	0.0	
Q1, Q3	-2.0, 1.0	-2.0, 1.0	
Min, Max	-8.0, 7.0	-9.0, 9.0	
Difference in Change from Baseline at Week 20			
n [1]	73	76	
n [2]	59	69	
MMRM: Least Squares Mean [SE] (95% CI)	0.02 [0.29] (-0.54, 0.59)	-0.48 [0.27] (-1.01, 0.05)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.51 [0.36] (-0.21, 1.22)		
MMRM: P-value	0.16		
Corrected Hedges' g (95% CI)	0.228 (-0.121, 0.576)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.91		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn02-db.pdf 29AUG2023: 9:38

Table 2.5902: Analysis of MPN-SAF Mean Questionnaire Item #2 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Abdominal Pain at Week 20 from Baseline			
n	39	43	
Mean (SD)	-20.8 (83.26)	-11.1 (156.81)	
Median	-50.0	-50.0	
Q1, Q3	-88.9, 25.0	-100.0, 0.0	
Min, Max	-100.0, 300.0	-100.0, 900.0	
Difference in Percent Change from Baseline at Week 20			
n [1]	46	47	
n [2]	39	43	
MMRM: Least Squares Mean [SE] (95% CI)	-9.41 [19.74] (-48.67, 29.84)	-8.76 [18.91] (-46.35, 28.83)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.66 [26.47] (-53.28, 51.97)		
MMRM: P-value	0.98		
Corrected Hedges' g (95% CI)	-0.005 (-0.439, 0.428)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.85		
MPN0102 - Abdominal Pain at Week 24			
n	65	82	
Mean (SD)	1.8 (2.39)	1.3 (1.84)	
Median	1.0	1.0	
Q1, Q3	0.0, 3.0	0.0, 2.0	
Min, Max	0.0, 10.0	0.0, 8.0	
Return Rate (%)	76%	87%	
Number of Subjects in Risk	70	87	
Return Rate in Risk (%)	93%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5902: Analysis of MPN-SAF Mean Questionnaire Item #2 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Change in Abdominal Pain at Week 24 from Baseline		
n	59	68
Mean (SD)	-0.7 (2.52)	-1.1 (2.54)
Median	0.0	0.0
Q1, Q3	-2.0, 0.0	-2.0, 0.0
Min, Max	-8.0, 7.0	-9.0, 5.0
Difference in Change from Baseline at Week 24		
n [1]	73	76
n [2]	59	68
MMRM: Least Squares Mean [SE] (95% CI)	-0.17 [0.27] (-0.70, 0.36)	-0.75 [0.25] (-1.25, -0.25)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.58 [0.33] (-0.07, 1.24)	
MMRM: P-value	0.082	
Corrected Hedges' g (95% CI)	0.282 (-0.069, 0.632)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.91	
Percent Change in Abdominal Pain at Week 24 from Baseline		
n	37	40
Mean (SD)	-37.1 (65.92)	-46.0 (71.26)
Median	-50.0	-66.7
Q1, Q3	-100.0, 0.0	-100.0, 0.0
Min, Max	-100.0, 200.0	-100.0, 250.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn02-db.pdf 29AUG2023: 9:38

Table 2.5902: Analysis of MPN-SAF Mean Questionnaire Item #2 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	46	47	
n [2]	37	40	
MMRM: Least Squares Mean [SE] (95% CI)	-23.56 [13.87] (-51.13, 4.02)		-28.60 [13.28] (-55.00, -2.21)
MMRM: Least Squares Mean Difference [SE] (95% CI)	5.05 [17.95] (-30.64, 40.73)		
MMRM: P-value	0.78		
Corrected Hedges' g (95% CI)	0.059 (-0.388, 0.507)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.38		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

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Table 2.5903: Analysis of MPN-SAF Mean Questionnaire Item #3 Score and Change from Baseline

Double-Blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
MPN0103 - Abdominal Discomfort at Baseline		
n	77	76
Mean (SD)	2.8 (2.88)	2.8 (3.06)
Median	2.0	2.0
Q1, Q3	0.0, 4.0	0.0, 4.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
MPN0103 - Abdominal Discomfort at Week 4		
n	76	90
Mean (SD)	2.0 (2.44)	2.0 (2.19)
Median	1.0	1.0
Q1, Q3	0.0, 3.0	0.0, 3.0
Min, Max	0.0, 10.0	0.0, 9.0
Return Rate (%)	88%	96%
Number of Subjects in Risk	82	94
Return Rate in Risk (%)	93%	96%
Change in Abdominal Discomfort at Week 4 from Baseline		
n	71	75
Mean (SD)	-0.7 (2.36)	-1.0 (2.24)
Median	0.0	0.0
Q1, Q3	-1.0, 0.0	-2.0, 0.0
Min, Max	-8.0, 6.0	-9.0, 2.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.

MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.

[1] Number of subjects with analysable data for one or more time points.

[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5903: Analysis of MPN-SAF Mean Questionnaire Item #3 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	73	76	
n [2]	71	75	
MMRM: Least Squares Mean [SE] (95% CI)	-0.51 [0.24] (-0.99, -0.02)	-0.75 [0.23] (-1.21, -0.29)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.24 [0.30] (-0.35, 0.83)		
MMRM: P-value	0.42		
Corrected Hedges' g (95% CI)	0.118 (-0.207, 0.443)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.37		
Percent Change in Abdominal Discomfort at Week 4 from Baseline			
n	46	53	
Mean (SD)	-20.9 (60.64)	-33.4 (60.69)	
Median	-33.3	-33.3	
Q1, Q3	-57.1, 0.0	-100.0, 0.0	
Min, Max	-100.0, 200.0	-100.0, 200.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	48	53	
n [2]	46	53	
MMRM: Least Squares Mean [SE] (95% CI)	-17.00 [9.51] (-35.87, 1.88)	-32.01 [8.79] (-49.47, -14.55)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	15.01 [12.19] (-9.19, 39.21)		
MMRM: P-value	0.22		
Corrected Hedges' g (95% CI)	0.232 (-0.164, 0.628)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.22		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn03-db.pdf 29AUG2023: 9:38

Table 2.5903: Analysis of MPN-SAF Mean Questionnaire Item #3 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
MPN0103 - Abdominal Discomfort at Week 8		
n	70	86
Mean (SD)	1.9 (2.35)	2.0 (2.21)
Median	1.0	1.0
Q1, Q3	0.0, 3.0	0.0, 3.0
Min, Max	0.0, 10.0	0.0, 8.0
Return Rate (%)	81%	91%
Number of Subjects in Risk	79	94
Return Rate in Risk (%)	89%	91%
Change in Abdominal Discomfort at Week 8 from Baseline		
n	65	73
Mean (SD)	-1.0 (2.00)	-0.9 (2.52)
Median	0.0	0.0
Q1, Q3	-2.0, 0.0	-2.0, 1.0
Min, Max	-6.0, 3.0	-9.0, 4.0
Difference in Change from Baseline at Week 8		
n [1]	73	76
n [2]	65	73
MMRM: Least Squares Mean [SE] (95% CI)	-0.57 [0.25] (-1.06, -0.08)	-0.74 [0.23] (-1.20, -0.28)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.17 [0.30] (-0.42, 0.76)	
MMRM: P-value	0.57	
Corrected Hedges' g (95% CI)	0.085 (-0.249, 0.420)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.81	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn03-db.pdf 29AUG2023: 9:38

Table 2.5903: Analysis of MPN-SAF Mean Questionnaire Item #3 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Abdominal Discomfort at Week 8 from Baseline			
n	42	51	
Mean (SD)	-38.6 (43.05)	-32.8 (66.46)	
Median	-41.7	-50.0	
Q1, Q3	-66.7, 0.0	-100.0, 0.0	
Min, Max	-100.0, 50.0	-100.0, 200.0	
Difference in Percent Change from Baseline at Week 8			
n [1]	48	53	
n [2]	42	51	
MMRM: Least Squares Mean [SE] (95% CI)	-31.09 [9.38] (-49.72, -12.47)	-32.91 [8.49] (-49.78, -16.04)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.82 [11.87] (-21.76, 25.39)		
MMRM: P-value	0.88		
Corrected Hedges' g (95% CI)	0.030 (-0.379, 0.438)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.67		
MPN0103 - Abdominal Discomfort at Week 12			
n	71	89	
Mean (SD)	2.1 (2.43)	1.9 (1.71)	
Median	1.0	2.0	
Q1, Q3	0.0, 3.0	1.0, 3.0	
Min, Max	0.0, 10.0	0.0, 8.0	
Return Rate (%)	83%	95%	
Number of Subjects in Risk	76	94	
Return Rate in Risk (%)	93%	95%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn03-db.pdf 29AUG2023: 9:38

Table 2.5903: Analysis of MPN-SAF Mean Questionnaire Item #3 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Abdominal Discomfort at Week 12 from Baseline			
n	65	74	
Mean (SD)	-0.7 (2.53)	-1.0 (2.59)	
Median	0.0	0.0	
Q1, Q3	-2.0, 0.0	-2.0, 1.0	
Min, Max	-9.0, 5.0	-9.0, 5.0	
Difference in Change from Baseline at Week 12			
n [1]	73	76	
n [2]	65	74	
MMRM: Least Squares Mean [SE] (95% CI)	-0.45 [0.26] (-0.96, 0.05)	-0.86 [0.24] (-1.33, -0.38)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.40 [0.31] (-0.22, 1.02)		
MMRM: P-value	0.20		
Corrected Hedges' g (95% CI)	0.193 (-0.141, 0.527)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.77		
Percent Change in Abdominal Discomfort at Week 12 from Baseline			
n	42	51	
Mean (SD)	-27.1 (68.48)	-39.5 (59.46)	
Median	-38.1	-50.0	
Q1, Q3	-83.3, 0.0	-80.0, 0.0	
Min, Max	-100.0, 150.0	-100.0, 200.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5903: Analysis of MPN-SAF Mean Questionnaire Item #3 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	48	53	
n [2]	42	51	
MMRM: Least Squares Mean [SE] (95% CI)	-20.76 [10.00] (-40.62, -0.91)		-37.90 [9.09] (-55.96, -19.85)
MMRM: Least Squares Mean Difference [SE] (95% CI)	17.14 [12.78] (-8.23, 42.51)		
MMRM: P-value	0.18		
Corrected Hedges' g (95% CI)	0.262 (-0.148, 0.672)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.29		
MPN0103 - Abdominal Discomfort at Week 16			
n	67	83	
Mean (SD)	2.3 (2.67)	1.8 (2.13)	
Median	2.0	1.0	
Q1, Q3	0.0, 4.0	0.0, 3.0	
Min, Max	0.0, 10.0	0.0, 8.0	
Return Rate (%)	78%	88%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	89%	91%	
Change in Abdominal Discomfort at Week 16 from Baseline			
n	61	71	
Mean (SD)	-0.5 (2.37)	-1.2 (2.54)	
Median	0.0	-1.0	
Q1, Q3	-2.0, 0.0	-2.0, 0.0	
Min, Max	-8.0, 7.0	-9.0, 7.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5903: Analysis of MPN-SAF Mean Questionnaire Item #3 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	73	76	
n [2]	61	71	
MMRM: Least Squares Mean [SE] (95% CI)	-0.13 [0.27] (-0.67, 0.41)	-0.93 [0.25] (-1.43, -0.43)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.80 [0.34] (0.13, 1.47)		
MMRM: P-value	0.019		
Corrected Hedges' g (95% CI)	0.374 (0.028, 0.719)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.11		
Percent Change in Abdominal Discomfort at Week 16 from Baseline			
n	40	50	
Mean (SD)	-18.2 (65.52)	-34.0 (117.93)	
Median	-25.0	-50.0	
Q1, Q3	-66.7, 12.5	-100.0, -25.0	
Min, Max	-100.0, 200.0	-100.0, 700.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	48	53	
n [2]	40	50	
MMRM: Least Squares Mean [SE] (95% CI)	-9.85 [15.33] (-40.29, 20.59)	-34.13 [13.83] (-61.59, -6.67)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	24.28 [20.17] (-15.77, 64.34)		
MMRM: P-value	0.23		
Corrected Hedges' g (95% CI)	0.247 (-0.170, 0.664)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.021		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5903: Analysis of MPN-SAF Mean Questionnaire Item #3 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
MPN0103 - Abdominal Discomfort at Week 20		
n	64	83
Mean (SD)	2.3 (2.85)	2.1 (2.08)
Median	1.0	2.0
Q1, Q3	0.0, 4.0	0.0, 3.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	74%	88%
Number of Subjects in Risk	74	90
Return Rate in Risk (%)	86%	92%
Change in Abdominal Discomfort at Week 20 from Baseline		
n	59	69
Mean (SD)	-0.5 (2.71)	-0.9 (2.53)
Median	0.0	-1.0
Q1, Q3	-2.0, 1.0	-2.0, 1.0
Min, Max	-8.0, 7.0	-9.0, 7.0
Difference in Change from Baseline at Week 20		
n [1]	73	76
n [2]	59	69
MMRM: Least Squares Mean [SE] (95% CI)	-0.13 [0.29] (-0.71, 0.45)	-0.60 [0.27] (-1.14, -0.06)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.48 [0.37] (-0.25, 1.20)	
MMRM: P-value	0.20	
Corrected Hedges' g (95% CI)	0.209 (-0.139, 0.558)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.43	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5903: Analysis of MPN-SAF Mean Questionnaire Item #3 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Abdominal Discomfort at Week 20 from Baseline			
n	40	49	
Mean (SD)	-21.6 (73.16)	-38.6 (62.68)	
Median	-41.4	-50.0	
Q1, Q3	-81.9, 29.2	-100.0, 0.0	
Min, Max	-100.0, 200.0	-100.0, 233.3	
Difference in Percent Change from Baseline at Week 20			
n [1]	48	53	
n [2]	40	49	
MMRM: Least Squares Mean [SE] (95% CI)	-16.74 [10.89] (-38.38, 4.89)	-38.05 [9.92] (-57.74, -18.36)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	21.31 [14.05] (-6.60, 49.22)		
MMRM: P-value	0.13		
Corrected Hedges' g (95% CI)	0.305 (-0.115, 0.725)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.33		
MPN0103 - Abdominal Discomfort at Week 24			
n	65	82	
Mean (SD)	2.0 (2.52)	1.6 (1.96)	
Median	1.0	1.0	
Q1, Q3	0.0, 3.0	0.0, 2.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	76%	87%	
Number of Subjects in Risk	70	87	
Return Rate in Risk (%)	93%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5903: Analysis of MPN-SAF Mean Questionnaire Item #3 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Change in Abdominal Discomfort at Week 24 from Baseline		
n	59	68
Mean (SD)	-0.8 (2.64)	-1.3 (2.40)
Median	0.0	-1.0
Q1, Q3	-2.0, 1.0	-2.0, 0.0
Min, Max	-8.0, 9.0	-9.0, 3.0
Difference in Change from Baseline at Week 24		
n [1]	73	76
n [2]	59	68
MMRM: Least Squares Mean [SE] (95% CI)	-0.40 [0.27] (-0.93, 0.14)	-0.97 [0.25] (-1.48, -0.47)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.58 [0.34] (-0.09, 1.24)	
MMRM: P-value	0.088	
Corrected Hedges' g (95% CI)	0.275 (-0.075, 0.625)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.30	
Percent Change in Abdominal Discomfort at Week 24 from Baseline		
n	38	46
Mean (SD)	-39.3 (56.95)	-54.2 (48.55)
Median	-50.0	-52.8
Q1, Q3	-100.0, 0.0	-100.0, -33.3
Min, Max	-100.0, 100.0	-100.0, 100.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5903: Analysis of MPN-SAF Mean Questionnaire Item #3 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	48	53	
n [2]	38	46	
MMRM: Least Squares Mean [SE] (95% CI)	-31.07 [8.85] (-48.64, -13.49)		-48.22 [8.08] (-64.26, -32.18)
MMRM: Least Squares Mean Difference [SE] (95% CI)	17.16 [11.13] (-4.95, 39.26)		
MMRM: P-value	0.13		
Corrected Hedges' g (95% CI)	0.311 (-0.121, 0.743)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.22		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5904: Analysis of MPN-SAF Mean Questionnaire Item #4 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
MPN0104 - Inactivity at Baseline		
n	77	76
Mean (SD)	3.5 (3.09)	3.4 (2.93)
Median	3.0	3.0
Q1, Q3	1.0, 6.0	0.0, 6.0
Min, Max	0.0, 10.0	0.0, 9.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
MPN0104 - Inactivity at Week 4		
n	76	90
Mean (SD)	3.1 (2.89)	2.7 (2.71)
Median	2.0	2.0
Q1, Q3	0.5, 5.5	0.0, 5.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	88%	96%
Number of Subjects in Risk	82	94
Return Rate in Risk (%)	93%	96%
Change in Inactivity at Week 4 from Baseline		
n	71	75
Mean (SD)	-0.1 (1.95)	-0.8 (2.35)
Median	0.0	0.0
Q1, Q3	-1.0, 1.0	-2.0, 0.0
Min, Max	-5.0, 6.0	-7.0, 5.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5904: Analysis of MPN-SAF Mean Questionnaire Item #4 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	73	76	
n [2]	71	75	
MMRM: Least Squares Mean [SE] (95% CI)	0.12 [0.27] (-0.42, 0.65)	-0.54 [0.26] (-1.05, -0.03)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.66 [0.33] (0.01, 1.31)		
MMRM: P-value	0.048		
Corrected Hedges' g (95% CI)	0.291 (-0.035, 0.617)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.14		
Percent Change in Inactivity at Week 4 from Baseline			
n	55	53	
Mean (SD)	16.8 (121.53)	-16.7 (73.91)	
Median	0.0	-33.3	
Q1, Q3	-40.0, 11.1	-62.5, 0.0	
Min, Max	-100.0, 600.0	-100.0, 250.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	56	54	
n [2]	55	53	
MMRM: Least Squares Mean [SE] (95% CI)	16.90 [14.48] (-11.83, 45.63)	-14.03 [14.35] (-42.49, 14.43)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	30.93 [19.01] (-6.77, 68.63)		
MMRM: P-value	0.11		
Corrected Hedges' g (95% CI)	0.290 (-0.089, 0.669)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.081		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5904: Analysis of MPN-SAF Mean Questionnaire Item #4 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPN0104 - Inactivity at Week 8			
n	70	86	
Mean (SD)	3.3 (2.66)	2.7 (2.50)	
Median	3.0	2.0	
Q1, Q3	1.0, 5.0	0.0, 4.0	
Min, Max	0.0, 10.0	0.0, 9.0	
Return Rate (%)	81%	91%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	91%	
Change in Inactivity at Week 8 from Baseline			
n	65	73	
Mean (SD)	0.1 (2.24)	-0.6 (2.44)	
Median	0.0	0.0	
Q1, Q3	-1.0, 1.0	-2.0, 0.0	
Min, Max	-5.0, 5.0	-8.0, 5.0	
Difference in Change from Baseline at Week 8			
n [1]	73	76	
n [2]	65	73	
MMRM: Least Squares Mean [SE] (95% CI)	0.41 [0.27] (-0.13, 0.96)	-0.46 [0.26] (-0.97, 0.05)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.87 [0.33] (0.21, 1.53)		
MMRM: P-value	0.010		
Corrected Hedges' g (95% CI)	0.391 (0.054, 0.729)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.059		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5904: Analysis of MPN-SAF Mean Questionnaire Item #4 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Inactivity at Week 8 from Baseline			
n	50	51	
Mean (SD)	16.6 (97.10)	-16.5 (66.03)	
Median	0.0	-20.0	
Q1, Q3	-42.9, 50.0	-60.0, 0.0	
Min, Max	-100.0, 500.0	-100.0, 200.0	
Difference in Percent Change from Baseline at Week 8			
n [1]	56	54	
n [2]	50	51	
MMRM: Least Squares Mean [SE] (95% CI)	16.03 [12.26] (-8.29, 40.34)		-14.85 [11.86] (-38.37, 8.67)
MMRM: Least Squares Mean Difference [SE] (95% CI)	30.88 [15.39] (0.36, 61.40)		
MMRM: P-value	0.047		
Corrected Hedges' g (95% CI)	0.358 (-0.036, 0.751)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.041		
MPN0104 - Inactivity at Week 12			
n	71	89	
Mean (SD)	3.2 (2.46)	2.7 (2.54)	
Median	3.0	2.0	
Q1, Q3	1.0, 5.0	0.0, 4.0	
Min, Max	0.0, 9.0	0.0, 9.0	
Return Rate (%)	83%	95%	
Number of Subjects in Risk	76	94	
Return Rate in Risk (%)	93%	95%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5904: Analysis of MPN-SAF Mean Questionnaire Item #4 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Change in Inactivity at Week 12 from Baseline		
n	65	74
Mean (SD)	0.1 (2.24)	-0.7 (2.51)
Median	0.0	0.0
Q1, Q3	-1.0, 1.0	-2.0, 1.0
Min, Max	-7.0, 7.0	-8.0, 7.0
Difference in Change from Baseline at Week 12		
n [1]	73	76
n [2]	65	74
MMRM: Least Squares Mean [SE] (95% CI)	0.45 [0.28] (-0.10, 0.99)	-0.44 [0.26] (-0.95, 0.07)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.89 [0.34] (0.23, 1.55)	
MMRM: P-value	0.009	
Corrected Hedges' g (95% CI)	0.398 (0.061, 0.734)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.009	
Percent Change in Inactivity at Week 12 from Baseline		
n	49	52
Mean (SD)	20.1 (102.51)	-7.2 (123.54)
Median	0.0	-33.3
Q1, Q3	-40.0, 50.0	-61.3, 0.0
Min, Max	-100.0, 500.0	-100.0, 700.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5904: Analysis of MPN-SAF Mean Questionnaire Item #4 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	56	54	
n [2]	49	52	
MMRM: Least Squares Mean [SE] (95% CI)	20.23 [15.92] (-11.35, 51.81)		-1.48 [15.42] (-32.06, 29.11)
MMRM: Least Squares Mean Difference [SE] (95% CI)	21.70 [20.91] (-19.77, 63.17)		
MMRM: P-value	0.30		
Corrected Hedges' g (95% CI)	0.193 (-0.198, 0.585)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.016		
MPN0104 - Inactivity at Week 16			
n	67	83	
Mean (SD)	3.1 (2.71)	2.6 (2.59)	
Median	3.0	2.0	
Q1, Q3	0.0, 5.0	0.0, 4.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	78%	88%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	89%	91%	
Change in Inactivity at Week 16 from Baseline			
n	61	71	
Mean (SD)	0.0 (2.74)	-0.7 (2.39)	
Median	0.0	0.0	
Q1, Q3	-1.0, 1.0	-2.0, 1.0	
Min, Max	-8.0, 8.0	-8.0, 6.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5904: Analysis of MPN-SAF Mean Questionnaire Item #4 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	73	76	
n [2]	61	71	
MMRM: Least Squares Mean [SE] (95% CI)	0.29 [0.30] (-0.31, 0.89)	-0.33 [0.28] (-0.89, 0.23)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.62 [0.38] (-0.13, 1.37)		
MMRM: P-value	0.10		
Corrected Hedges' g (95% CI)	0.257 (-0.086, 0.601)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.15		
Percent Change in Inactivity at Week 16 from Baseline			
n	47	50	
Mean (SD)	30.8 (136.84)	-17.9 (69.31)	
Median	0.0	-20.0	
Q1, Q3	-40.0, 25.0	-60.0, 0.0	
Min, Max	-100.0, 500.0	-100.0, 300.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	56	54	
n [2]	47	50	
MMRM: Least Squares Mean [SE] (95% CI)	31.23 [15.56] (0.37, 62.09)	-6.78 [15.20] (-36.94, 23.38)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	38.01 [20.47] (-2.59, 78.60)		
MMRM: P-value	0.066		
Corrected Hedges' g (95% CI)	0.352 (-0.049, 0.753)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.025		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5904: Analysis of MPN-SAF Mean Questionnaire Item #4 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
MPN0104 - Inactivity at Week 20		
n	64	83
Mean (SD)	3.1 (2.74)	2.6 (2.36)
Median	3.0	2.0
Q1, Q3	0.5, 5.0	0.0, 4.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	74%	88%
Number of Subjects in Risk	74	90
Return Rate in Risk (%)	86%	92%
Change in Inactivity at Week 20 from Baseline		
n	59	69
Mean (SD)	-0.1 (2.44)	-0.7 (2.45)
Median	0.0	0.0
Q1, Q3	-1.0, 1.0	-2.0, 1.0
Min, Max	-8.0, 8.0	-8.0, 5.0
Difference in Change from Baseline at Week 20		
n [1]	73	76
n [2]	59	69
MMRM: Least Squares Mean [SE] (95% CI)	0.28 [0.29] (-0.29, 0.84)	-0.42 [0.27] (-0.95, 0.11)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.70 [0.35] (0.00, 1.39)	
MMRM: P-value	0.050	
Corrected Hedges' g (95% CI)	0.313 (-0.037, 0.662)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.30	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5904: Analysis of MPN-SAF Mean Questionnaire Item #4 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Inactivity at Week 20 from Baseline			
n	45	48	
Mean (SD)	34.9 (165.87)	-21.4 (62.54)	
Median	0.0	-31.0	
Q1, Q3	-33.3, 33.3	-57.1, 0.0	
Min, Max	-100.0, 800.0	-100.0, 250.0	
Difference in Percent Change from Baseline at Week 20			
n [1]	56	54	
n [2]	45	48	
MMRM: Least Squares Mean [SE] (95% CI)	43.39 [18.99] (5.72, 81.06)	-9.97 [18.55] (-46.77, 26.82)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	53.36 [25.51] (2.77, 103.95)		
MMRM: P-value	0.039		
Corrected Hedges' g (95% CI)	0.414 (0.003, 0.825)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.057		
MPN0104 - Inactivity at Week 24			
n	65	82	
Mean (SD)	3.0 (2.50)	2.4 (2.39)	
Median	3.0	2.0	
Q1, Q3	1.0, 5.0	1.0, 4.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	76%	87%	
Number of Subjects in Risk	70	87	
Return Rate in Risk (%)	93%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5904: Analysis of MPN-SAF Mean Questionnaire Item #4 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Change in Inactivity at Week 24 from Baseline		
n	59	68
Mean (SD)	0.0 (2.64)	-0.8 (2.45)
Median	0.0	0.0
Q1, Q3	-1.0, 1.0	-2.0, 1.0
Min, Max	-8.0, 7.0	-8.0, 4.0
Difference in Change from Baseline at Week 24		
n [1]	73	76
n [2]	59	68
MMRM: Least Squares Mean [SE] (95% CI)	0.40 [0.30] (-0.18, 0.99)	-0.50 [0.28] (-1.05, 0.05)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.91 [0.37] (0.18, 1.63)	
MMRM: P-value	0.015	
Corrected Hedges' g (95% CI)	0.394 (0.042, 0.746)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.070	
Percent Change in Inactivity at Week 24 from Baseline		
n	44	46
Mean (SD)	26.4 (154.63)	-27.1 (58.61)
Median	0.0	-45.0
Q1, Q3	-50.0, 18.3	-66.7, 0.0
Min, Max	-100.0, 700.0	-100.0, 200.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5904: Analysis of MPN-SAF Mean Questionnaire Item #4 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	56	54	
n [2]	44	46	
MMRM: Least Squares Mean [SE] (95% CI)	40.77 [19.87] (1.35, 80.19)		-10.64 [19.37] (-49.05, 27.78)
MMRM: Least Squares Mean Difference [SE] (95% CI)	51.40 [26.76] (-1.68, 104.48)		
MMRM: P-value	0.058		
Corrected Hedges' g (95% CI)	0.387 (-0.030, 0.804)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.033		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.5905: Analysis of MPN-SAF Mean Questionnaire Item #5 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
MPN0105 - Headaches at Baseline		
n	77	76
Mean (SD)	1.4 (2.32)	1.5 (2.37)
Median	0.0	0.0
Q1, Q3	0.0, 2.0	0.0, 2.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
MPN0105 - Headaches at Week 4		
n	76	90
Mean (SD)	1.3 (2.21)	1.2 (2.12)
Median	0.0	0.0
Q1, Q3	0.0, 1.0	0.0, 1.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	88%	96%
Number of Subjects in Risk	82	94
Return Rate in Risk (%)	93%	96%
Change in Headaches at Week 4 from Baseline		
n	71	75
Mean (SD)	-0.3 (2.13)	-0.3 (1.91)
Median	0.0	0.0
Q1, Q3	-1.0, 0.0	-1.0, 0.0
Min, Max	-9.0, 7.0	-7.0, 7.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5905: Analysis of MPN-SAF Mean Questionnaire Item #5 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	73	76	
n [2]	71	75	
MMRM: Least Squares Mean [SE] (95% CI)	-0.01 [0.22] (-0.44, 0.42)	-0.14 [0.21] (-0.56, 0.27)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.13 [0.28] (-0.41, 0.68)		
MMRM: P-value	0.63		
Corrected Hedges' g (95% CI)	0.072 (-0.252, 0.397)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.34		
Percent Change in Headaches at Week 4 from Baseline			
n	30	35	
Mean (SD)	-19.4 (111.58)	-31.7 (84.94)	
Median	-41.7	-50.0	
Q1, Q3	-100.0, 0.0	-100.0, 0.0	
Min, Max	-100.0, 400.0	-100.0, 200.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	31	35	
n [2]	30	35	
MMRM: Least Squares Mean [SE] (95% CI)	-17.45 [18.72] (-54.92, 20.02)	-30.93 [16.94] (-64.83, 2.98)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	13.48 [24.70] (-35.96, 62.92)		
MMRM: P-value	0.59		
Corrected Hedges' g (95% CI)	0.131 (-0.357, 0.620)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.50		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5905: Analysis of MPN-SAF Mean Questionnaire Item #5 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPN0105 - Headaches at Week 8			
n	70	86	
Mean (SD)	1.3 (2.08)	1.1 (2.02)	
Median	0.0	0.0	
Q1, Q3	0.0, 2.0	0.0, 1.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	81%	91%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	91%	
Change in Headaches at Week 8 from Baseline			
n	65	73	
Mean (SD)	-0.1 (1.92)	-0.4 (2.10)	
Median	0.0	0.0	
Q1, Q3	-1.0, 1.0	-1.0, 0.0	
Min, Max	-7.0, 5.0	-8.0, 6.0	
Difference in Change from Baseline at Week 8			
n [1]	73	76	
n [2]	65	73	
MMRM: Least Squares Mean [SE] (95% CI)	0.16 [0.23] (-0.30, 0.61)	-0.18 [0.22] (-0.61, 0.25)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.34 [0.29] (-0.24, 0.91)		
MMRM: P-value	0.25		
Corrected Hedges' g (95% CI)	0.181 (-0.154, 0.516)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.47		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5905: Analysis of MPN-SAF Mean Questionnaire Item #5 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Headaches at Week 8 from Baseline		
n	27	34
Mean (SD)	-43.3 (62.00)	-34.8 (85.55)
Median	-57.1	-64.6
Q1, Q3	-100.0, 0.0	-100.0, 0.0
Min, Max	-100.0, 100.0	-100.0, 300.0
Difference in Percent Change from Baseline at Week 8		
n [1]	31	35
n [2]	27	34
MMRM: Least Squares Mean [SE] (95% CI)	-35.97 [15.91] (-67.82, -4.12)	-34.85 [13.87] (-62.61, -7.10)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.11 [20.40] (-41.95, 39.72)	
MMRM: P-value	0.96	
Corrected Hedges' g (95% CI)	-0.013 (-0.519, 0.492)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.92	
MPN0105 - Headaches at Week 12		
n	71	89
Mean (SD)	1.5 (2.20)	1.3 (2.03)
Median	1.0	0.0
Q1, Q3	0.0, 2.0	0.0, 2.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	83%	95%
Number of Subjects in Risk	76	94
Return Rate in Risk (%)	93%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5905: Analysis of MPN-SAF Mean Questionnaire Item #5 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Change in Headaches at Week 12 from Baseline		
n	65	74
Mean (SD)	0.0 (2.52)	-0.2 (2.19)
Median	0.0	0.0
Q1, Q3	-1.0, 1.0	-1.0, 1.0
Min, Max	-9.0, 7.0	-8.0, 5.0
Difference in Change from Baseline at Week 12		
n [1]	73	76
n [2]	65	74
MMRM: Least Squares Mean [SE] (95% CI)	0.27 [0.26] (-0.24, 0.77)	0.00 [0.24] (-0.47, 0.48)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.26 [0.33] (-0.38, 0.91)	
MMRM: P-value	0.42	
Corrected Hedges' g (95% CI)	0.128 (-0.206, 0.461)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.90	
Percent Change in Headaches at Week 12 from Baseline		
n	29	35
Mean (SD)	-34.7 (81.73)	-6.7 (131.24)
Median	-37.5	-50.0
Q1, Q3	-100.0, 0.0	-100.0, 50.0
Min, Max	-100.0, 300.0	-100.0, 500.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5905: Analysis of MPN-SAF Mean Questionnaire Item #5 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	31	35	
n [2]	29	35	
MMRM: Least Squares Mean [SE] (95% CI)	-24.04 [21.85] (-67.77, 19.69)	-5.93 [19.67] (-45.31, 33.45)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-18.11 [28.93] (-76.01, 39.79)		
MMRM: P-value	0.53		
Corrected Hedges' g (95% CI)	-0.153 (-0.646, 0.340)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.56		
MPN0105 - Headaches at Week 16			
n	67	83	
Mean (SD)	1.2 (2.01)	1.2 (1.96)	
Median	0.0	0.0	
Q1, Q3	0.0, 2.0	0.0, 2.0	
Min, Max	0.0, 8.0	0.0, 10.0	
Return Rate (%)	78%	88%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	89%	91%	
Change in Headaches at Week 16 from Baseline			
n	61	71	
Mean (SD)	-0.4 (2.60)	-0.5 (2.18)	
Median	0.0	0.0	
Q1, Q3	-1.0, 0.0	-1.0, 0.0	
Min, Max	-9.0, 8.0	-8.0, 6.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5905: Analysis of MPN-SAF Mean Questionnaire Item #5 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	73	76	
n [2]	61	71	
MMRM: Least Squares Mean [SE] (95% CI)	-0.02 [0.25] (-0.51, 0.46)	-0.23 [0.23] (-0.69, 0.22)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.21 [0.31] (-0.41, 0.83)		
MMRM: P-value	0.51		
Corrected Hedges' g (95% CI)	0.107 (-0.236, 0.449)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.94		
Percent Change in Headaches at Week 16 from Baseline			
n	28	34	
Mean (SD)	-44.2 (70.43)	-35.9 (70.90)	
Median	-58.3	-50.0	
Q1, Q3	-100.0, 0.0	-100.0, 0.0	
Min, Max	-100.0, 200.0	-100.0, 100.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	31	35	
n [2]	28	34	
MMRM: Least Squares Mean [SE] (95% CI)	-35.92 [14.82] (-65.58, -6.27)	-36.75 [13.10] (-62.97, -10.53)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.82 [19.04] (-37.29, 38.94)		
MMRM: P-value	0.97		
Corrected Hedges' g (95% CI)	0.011 (-0.490, 0.511)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.82		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5905: Analysis of MPN-SAF Mean Questionnaire Item #5 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPN0105 - Headaches at Week 20			
n	64	83	
Mean (SD)	1.4 (2.29)	0.9 (1.56)	
Median	0.0	0.0	
Q1, Q3	0.0, 2.0	0.0, 1.0	
Min, Max	0.0, 10.0	0.0, 8.0	
Return Rate (%)	74%	88%	
Number of Subjects in Risk	74	90	
Return Rate in Risk (%)	86%	92%	
Change in Headaches at Week 20 from Baseline			
n	59	69	
Mean (SD)	-0.1 (2.66)	-0.7 (2.03)	
Median	0.0	0.0	
Q1, Q3	-1.0, 1.0	-1.0, 0.0	
Min, Max	-6.0, 10.0	-8.0, 4.0	
Difference in Change from Baseline at Week 20			
n [1]	73	76	
n [2]	59	69	
MMRM: Least Squares Mean [SE] (95% CI)	0.16 [0.24] (-0.32, 0.63)	-0.49 [0.22] (-0.93, -0.04)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.64 [0.30] (0.05, 1.24)		
MMRM: P-value	0.035		
Corrected Hedges' g (95% CI)	0.347 (-0.003, 0.697)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.16		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5905: Analysis of MPN-SAF Mean Questionnaire Item #5 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Headaches at Week 20 from Baseline		
n	26	32
Mean (SD)	-35.1 (80.30)	-29.1 (110.67)
Median	-63.3	-58.3
Q1, Q3	-100.0, 0.0	-100.0, -18.3
Min, Max	-100.0, 200.0	-100.0, 400.0
Difference in Percent Change from Baseline at Week 20		
n [1]	31	35
n [2]	26	32
MMRM: Least Squares Mean [SE] (95% CI)	-32.68 [19.23] (-71.17, 5.82)	-29.89 [17.04] (-64.01, 4.23)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.79 [25.12] (-53.08, 47.50)	
MMRM: P-value	0.91	
Corrected Hedges' g (95% CI)	-0.028 (-0.546, 0.489)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.64	
MPN0105 - Headaches at Week 24		
n	65	82
Mean (SD)	0.9 (1.61)	1.0 (2.18)
Median	0.0	0.0
Q1, Q3	0.0, 1.0	0.0, 1.0
Min, Max	0.0, 8.0	0.0, 10.0
Return Rate (%)	76%	87%
Number of Subjects in Risk	70	87
Return Rate in Risk (%)	93%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5905: Analysis of MPN-SAF Mean Questionnaire Item #5 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Change in Headaches at Week 24 from Baseline		
n	59	68
Mean (SD)	-0.7 (1.85)	-0.5 (2.03)
Median	0.0	0.0
Q1, Q3	-1.0, 0.0	-1.0, 0.0
Min, Max	-6.0, 3.0	-8.0, 7.0
Difference in Change from Baseline at Week 24		
n [1]	73	76
n [2]	59	68
MMRM: Least Squares Mean [SE] (95% CI)	-0.33 [0.21] (-0.74, 0.08)	-0.30 [0.19] (-0.68, 0.09)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.04 [0.25] (-0.54, 0.47)	
MMRM: P-value	0.89	
Corrected Hedges' g (95% CI)	-0.022 (-0.371, 0.326)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.64	
Percent Change in Headaches at Week 24 from Baseline		
n	27	29
Mean (SD)	-54.1 (59.95)	-34.7 (102.32)
Median	-66.7	-75.0
Q1, Q3	-100.0, 0.0	-100.0, 0.0
Min, Max	-100.0, 100.0	-100.0, 350.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5905: Analysis of MPN-SAF Mean Questionnaire Item #5 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	31	35	
n [2]	27	29	
MMRM: Least Squares Mean [SE] (95% CI)	-46.34 [16.94] (-80.26, -12.43)	-32.97 [15.80] (-64.59, -1.36)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-13.37 [22.39] (-58.19, 31.45)		
MMRM: P-value	0.55		
Corrected Hedges' g (95% CI)	-0.152 (-0.677, 0.373)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.67		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5906: Analysis of MPN-SAF Mean Questionnaire Item #6 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
MPN0106 - Concentration at Baseline		
n	77	76
Mean (SD)	2.4 (2.67)	2.8 (2.79)
Median	1.0	2.0
Q1, Q3	0.0, 4.0	0.0, 5.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
MPN0106 - Concentration at Week 4		
n	76	90
Mean (SD)	2.2 (2.51)	2.1 (2.39)
Median	2.0	1.0
Q1, Q3	0.0, 3.0	0.0, 4.0
Min, Max	0.0, 10.0	0.0, 9.0
Return Rate (%)	88%	96%
Number of Subjects in Risk	82	94
Return Rate in Risk (%)	93%	96%
Change in Concentration at Week 4 from Baseline		
n	71	75
Mean (SD)	-0.3 (2.35)	-0.7 (2.47)
Median	0.0	-1.0
Q1, Q3	-1.0, 1.0	-2.0, 0.0
Min, Max	-9.0, 5.0	-8.0, 5.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5906: Analysis of MPN-SAF Mean Questionnaire Item #6 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	73	76	
n [2]	71	75	
MMRM: Least Squares Mean [SE] (95% CI)	0.05 [0.26] (-0.47, 0.56)	-0.29 [0.25] (-0.79, 0.21)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.34 [0.33] (-0.32, 0.99)		
MMRM: P-value	0.31		
Corrected Hedges' g (95% CI)	0.153 (-0.172, 0.478)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.12		
Percent Change in Concentration at Week 4 from Baseline			
n	47	53	
Mean (SD)	5.1 (109.80)	-30.8 (77.93)	
Median	-12.5	-50.0	
Q1, Q3	-60.0, 20.0	-100.0, 0.0	
Min, Max	-100.0, 400.0	-100.0, 200.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	47	53	
n [2]	47	53	
MMRM: Least Squares Mean [SE] (95% CI)	11.92 [15.20] (-18.28, 42.11)	-23.00 [14.12] (-51.04, 5.04)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	34.92 [19.16] (-3.14, 72.97)		
MMRM: P-value	0.072		
Corrected Hedges' g (95% CI)	0.335 (-0.061, 0.730)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.025		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5906: Analysis of MPN-SAF Mean Questionnaire Item #6 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPN0106 - Concentration at Week 8			
n	70	86	
Mean (SD)	2.2 (2.18)	1.9 (2.16)	
Median	2.0	1.0	
Q1, Q3	0.0, 4.0	0.0, 3.0	
Min, Max	0.0, 8.0	0.0, 8.0	
Return Rate (%)	81%	91%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	91%	
Change in Concentration at Week 8 from Baseline			
n	65	73	
Mean (SD)	-0.2 (2.25)	-0.8 (2.31)	
Median	0.0	0.0	
Q1, Q3	-1.0, 1.0	-2.0, 0.0	
Min, Max	-7.0, 5.0	-8.0, 3.0	
Difference in Change from Baseline at Week 8			
n [1]	73	76	
n [2]	65	73	
MMRM: Least Squares Mean [SE] (95% CI)		0.15 [0.25] (-0.33, 0.64)	-0.41 [0.23] (-0.87, 0.04)
MMRM: Least Squares Mean Difference [SE] (95% CI)		0.57 [0.30] (-0.04, 1.17)	
MMRM: P-value		0.065	
Corrected Hedges' g (95% CI)		0.285 (-0.051, 0.621)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value		0.086	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5906: Analysis of MPN-SAF Mean Questionnaire Item #6 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Concentration at Week 8 from Baseline		
n	42	51
Mean (SD)	-0.7 (110.53)	-27.4 (64.03)
Median	-6.3	-40.0
Q1, Q3	-77.8, 25.0	-66.7, 0.0
Min, Max	-100.0, 500.0	-100.0, 150.0
Difference in Percent Change from Baseline at Week 8		
n [1]	47	53
n [2]	42	51
MMRM: Least Squares Mean [SE] (95% CI)	9.34 [14.24] (-18.94, 37.62)	-18.63 [13.00] (-44.45, 7.20)
MMRM: Least Squares Mean Difference [SE] (95% CI)	27.97 [17.57] (-6.93, 62.87)	
MMRM: P-value	0.11	
Corrected Hedges' g (95% CI)	0.300 (-0.111, 0.710)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.20	
MPN0106 - Concentration at Week 12		
n	71	89
Mean (SD)	2.3 (2.31)	1.9 (2.24)
Median	2.0	1.0
Q1, Q3	0.0, 3.0	0.0, 3.0
Min, Max	0.0, 10.0	0.0, 9.0
Return Rate (%)	83%	95%
Number of Subjects in Risk	76	94
Return Rate in Risk (%)	93%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5906: Analysis of MPN-SAF Mean Questionnaire Item #6 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Concentration at Week 12 from Baseline			
n	65	74	
Mean (SD)	0.1 (2.32)	-0.9 (2.31)	
Median	0.0	0.0	
Q1, Q3	-1.0, 1.0	-2.0, 0.0	
Min, Max	-7.0, 5.0	-8.0, 3.0	
Difference in Change from Baseline at Week 12			
n [1]	73	76	
n [2]	65	74	
MMRM: Least Squares Mean [SE] (95% CI)	0.38 [0.25] (-0.12, 0.88)	-0.49 [0.24] (-0.96, -0.01)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.86 [0.32] (0.24, 1.49)		
MMRM: P-value	0.007		
Corrected Hedges' g (95% CI)	0.420 (0.083, 0.756)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.012		
Percent Change in Concentration at Week 12 from Baseline			
n	42	51	
Mean (SD)	26.5 (134.11)	-32.8 (63.23)	
Median	0.0	-50.0	
Q1, Q3	-50.0, 60.0	-100.0, 0.0	
Min, Max	-100.0, 500.0	-100.0, 100.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5906: Analysis of MPN-SAF Mean Questionnaire Item #6 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	47	53	
n [2]	42	51	
MMRM: Least Squares Mean [SE] (95% CI)	35.28 [15.88] (3.74, 66.83)		-22.83 [14.58] (-51.79, 6.13)
MMRM: Least Squares Mean Difference [SE] (95% CI)	58.11 [20.05] (18.29, 97.93)		
MMRM: P-value	0.005		
Corrected Hedges' g (95% CI)	0.556 (0.140, 0.972)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.017		
MPN0106 - Concentration at Week 16			
n	67	83	
Mean (SD)	2.3 (2.48)	2.0 (2.18)	
Median	2.0	2.0	
Q1, Q3	0.0, 3.0	0.0, 3.0	
Min, Max	0.0, 10.0	0.0, 8.0	
Return Rate (%)	78%	88%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	89%	91%	
Change in Concentration at Week 16 from Baseline			
n	61	71	
Mean (SD)	0.1 (2.25)	-0.9 (2.39)	
Median	0.0	0.0	
Q1, Q3	-1.0, 1.0	-2.0, 0.0	
Min, Max	-6.0, 5.0	-8.0, 6.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5906: Analysis of MPN-SAF Mean Questionnaire Item #6 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	73	76	
n [2]	61	71	
MMRM: Least Squares Mean [SE] (95% CI)	0.34 [0.27] (-0.19, 0.87)	-0.41 [0.25] (-0.91, 0.09)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.75 [0.34] (0.08, 1.42)		
MMRM: P-value	0.029		
Corrected Hedges' g (95% CI)	0.352 (0.007, 0.696)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.013		
Percent Change in Concentration at Week 16 from Baseline			
n	39	50	
Mean (SD)	21.8 (126.16)	-31.4 (67.24)	
Median	0.0	-40.0	
Q1, Q3	-66.7, 66.7	-100.0, 0.0	
Min, Max	-100.0, 500.0	-100.0, 200.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	47	53	
n [2]	39	50	
MMRM: Least Squares Mean [SE] (95% CI)	26.16 [15.76] (-5.15, 57.46)	-22.49 [14.36] (-51.01, 6.04)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	48.64 [19.78] (9.35, 87.93)		
MMRM: P-value	0.016		
Corrected Hedges' g (95% CI)	0.481 (0.057, 0.906)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.11		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5906: Analysis of MPN-SAF Mean Questionnaire Item #6 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPN0106 - Concentration at Week 20			
n	64	83	
Mean (SD)	2.2 (2.33)	2.0 (2.06)	
Median	2.0	2.0	
Q1, Q3	0.0, 3.0	0.0, 3.0	
Min, Max	0.0, 10.0	0.0, 7.0	
Return Rate (%)	74%	88%	
Number of Subjects in Risk	74	90	
Return Rate in Risk (%)	86%	92%	
Change in Concentration at Week 20 from Baseline			
n	59	69	
Mean (SD)	-0.1 (2.27)	-1.0 (2.46)	
Median	0.0	0.0	
Q1, Q3	-1.0, 1.0	-2.0, 0.0	
Min, Max	-7.0, 5.0	-9.0, 4.0	
Difference in Change from Baseline at Week 20			
n [1]	73	76	
n [2]	59	69	
MMRM: Least Squares Mean [SE] (95% CI)	0.13 [0.25] (-0.36, 0.62)	-0.49 [0.23] (-0.95, -0.03)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.62 [0.31] (0.01, 1.23)		
MMRM: P-value	0.047		
Corrected Hedges' g (95% CI)	0.319 (-0.030, 0.669)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.009		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5906: Analysis of MPN-SAF Mean Questionnaire Item #6 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Concentration at Week 20 from Baseline		
n	39	49
Mean (SD)	20.8 (115.91)	-35.7 (58.35)
Median	0.0	-40.0
Q1, Q3	-50.0, 66.7	-87.5, 0.0
Min, Max	-100.0, 500.0	-100.0, 150.0
Difference in Percent Change from Baseline at Week 20		
n [1]	47	53
n [2]	39	49
MMRM: Least Squares Mean [SE] (95% CI)	27.73 [14.14] (-0.36, 55.82)	-24.81 [12.88] (-50.39, 0.77)
MMRM: Least Squares Mean Difference [SE] (95% CI)	52.54 [17.40] (17.98, 87.11)	
MMRM: P-value	0.003	
Corrected Hedges' g (95% CI)	0.583 (0.154, 1.012)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.009	
MPN0106 - Concentration at Week 24		
n	65	82
Mean (SD)	1.9 (2.04)	1.8 (2.09)
Median	2.0	1.0
Q1, Q3	0.0, 3.0	0.0, 3.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	76%	87%
Number of Subjects in Risk	70	87
Return Rate in Risk (%)	93%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5906: Analysis of MPN-SAF Mean Questionnaire Item #6 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Change in Concentration at Week 24 from Baseline		
n	59	68
Mean (SD)	-0.3 (2.37)	-1.0 (2.14)
Median	0.0	0.0
Q1, Q3	-1.0, 1.0	-2.0, 0.0
Min, Max	-7.0, 5.0	-8.0, 3.0
Difference in Change from Baseline at Week 24		
n [1]	73	76
n [2]	59	68
MMRM: Least Squares Mean [SE] (95% CI)	0.02 [0.23] (-0.43, 0.47)	-0.59 [0.22] (-1.02, -0.17)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.61 [0.28] (0.06, 1.16)	
MMRM: P-value	0.030	
Corrected Hedges' g (95% CI)	0.343 (-0.008, 0.694)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.016	
Percent Change in Concentration at Week 24 from Baseline		
n	38	46
Mean (SD)	-4.8 (84.84)	-40.8 (47.29)
Median	-20.8	-50.0
Q1, Q3	-75.0, 66.7	-75.0, 0.0
Min, Max	-100.0, 200.0	-100.0, 50.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5906: Analysis of MPN-SAF Mean Questionnaire Item #6 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	47	53	
n [2]	38	46	
MMRM: Least Squares Mean [SE] (95% CI)	11.27 [13.18] (-14.91, 37.44)		-27.39 [12.08] (-51.39, -3.39)
MMRM: Least Squares Mean Difference [SE] (95% CI)	38.66 [15.96] (6.96, 70.36)		
MMRM: P-value	0.017		
Corrected Hedges' g (95% CI)	0.469 (0.034, 0.905)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.10		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

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Table 2.5907: Analysis of MPN-SAF Mean Questionnaire Item #7 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
MPN0107 - Dizziness at Baseline		
n	77	76
Mean (SD)	2.2 (2.92)	2.1 (2.54)
Median	1.0	1.0
Q1, Q3	0.0, 4.0	0.0, 3.0
Min, Max	0.0, 10.0	0.0, 8.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
MPN0107 - Dizziness at Week 4		
n	76	90
Mean (SD)	1.9 (2.46)	2.0 (2.42)
Median	1.0	1.0
Q1, Q3	0.0, 3.0	0.0, 3.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	88%	96%
Number of Subjects in Risk	82	94
Return Rate in Risk (%)	93%	96%
Change in Dizziness at Week 4 from Baseline		
n	71	75
Mean (SD)	-0.4 (2.98)	-0.2 (2.19)
Median	0.0	0.0
Q1, Q3	-1.0, 1.0	-1.0, 0.0
Min, Max	-10.0, 7.0	-6.0, 7.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5907: Analysis of MPN-SAF Mean Questionnaire Item #7 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	73	76	
n [2]	71	75	
MMRM: Least Squares Mean [SE] (95% CI)	-0.20 [0.27] (-0.74, 0.34)	-0.24 [0.26] (-0.75, 0.28)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.04 [0.34] (-0.64, 0.72)		
MMRM: P-value	0.92		
Corrected Hedges' g (95% CI)	0.016 (-0.309, 0.340)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.54		
Percent Change in Dizziness at Week 4 from Baseline			
n	38	46	
Mean (SD)	-8.3 (110.68)	-6.9 (83.70)	
Median	-26.7	-6.3	
Q1, Q3	-100.0, 14.3	-66.7, 0.0	
Min, Max	-100.0, 400.0	-100.0, 233.3	
Difference in Percent Change from Baseline at Week 4			
n [1]	39	47	
n [2]	38	46	
MMRM: Least Squares Mean [SE] (95% CI)	-0.42 [16.06] (-32.40, 31.56)	-9.19 [14.10] (-37.25, 18.87)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	8.77 [20.60] (-32.25, 49.79)		
MMRM: P-value	0.67		
Corrected Hedges' g (95% CI)	0.089 (-0.340, 0.519)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.61		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5907: Analysis of MPN-SAF Mean Questionnaire Item #7 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPN0107 - Dizziness at Week 8			
n	70	86	
Mean (SD)	2.3 (2.65)	1.2 (1.71)	
Median	1.0	0.0	
Q1, Q3	0.0, 3.0	0.0, 2.0	
Min, Max	0.0, 9.0	0.0, 7.0	
Return Rate (%)	81%	91%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	91%	
Change in Dizziness at Week 8 from Baseline			
n	65	73	
Mean (SD)	0.0 (2.83)	-0.6 (2.31)	
Median	0.0	0.0	
Q1, Q3	-1.0, 1.0	-1.0, 0.0	
Min, Max	-7.0, 8.0	-8.0, 5.0	
Difference in Change from Baseline at Week 8			
n [1]	73	76	
n [2]	65	73	
MMRM: Least Squares Mean [SE] (95% CI)	0.24 [0.27] (-0.29, 0.77)	-0.75 [0.25] (-1.25, -0.25)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.99 [0.33] (0.33, 1.65)		
MMRM: P-value	0.003		
Corrected Hedges' g (95% CI)	0.458 (0.119, 0.797)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.19		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5907: Analysis of MPN-SAF Mean Questionnaire Item #7 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Dizziness at Week 8 from Baseline		
n	35	45
Mean (SD)	13.4 (185.62)	-37.8 (61.06)
Median	-30.0	-50.0
Q1, Q3	-80.0, 0.0	-100.0, 0.0
Min, Max	-100.0, 800.0	-100.0, 150.0
Difference in Percent Change from Baseline at Week 8		
n [1]	39	47
n [2]	35	45
MMRM: Least Squares Mean [SE] (95% CI)	24.67 [21.40] (-17.93, 67.26)	-41.55 [18.61] (-78.60, -4.49)
MMRM: Least Squares Mean Difference [SE] (95% CI)	66.22 [27.72] (11.04, 121.40)	
MMRM: P-value	0.019	
Corrected Hedges' g (95% CI)	0.522 (0.073, 0.971)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.44	
MPN0107 - Dizziness at Week 12		
n	71	89
Mean (SD)	2.2 (2.33)	1.6 (1.82)
Median	1.0	1.0
Q1, Q3	0.0, 3.0	0.0, 3.0
Min, Max	0.0, 8.0	0.0, 7.0
Return Rate (%)	83%	95%
Number of Subjects in Risk	76	94
Return Rate in Risk (%)	93%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5907: Analysis of MPN-SAF Mean Questionnaire Item #7 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Change in Dizziness at Week 12 from Baseline		
n	65	74
Mean (SD)	0.0 (2.94)	-0.5 (2.15)
Median	0.0	0.0
Q1, Q3	-1.0, 1.0	-1.0, 1.0
Min, Max	-10.0, 8.0	-8.0, 6.0
Difference in Change from Baseline at Week 12		
n [1]	73	76
n [2]	65	74
MMRM: Least Squares Mean [SE] (95% CI)	0.15 [0.26] (-0.36, 0.66)	-0.55 [0.24] (-1.02, -0.07)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.70 [0.32] (0.07, 1.32)	
MMRM: P-value	0.029	
Corrected Hedges' g (95% CI)	0.334 (-0.001, 0.670)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.057	
Percent Change in Dizziness at Week 12 from Baseline		
n	36	45
Mean (SD)	9.3 (141.17)	-31.9 (62.38)
Median	-16.7	-50.0
Q1, Q3	-64.6, 33.3	-100.0, 0.0
Min, Max	-100.0, 700.0	-100.0, 150.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5907: Analysis of MPN-SAF Mean Questionnaire Item #7 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	39	47	
n [2]	36	45	
MMRM: Least Squares Mean [SE] (95% CI)	14.66 [17.02] (-19.23, 48.55)		-34.79 [14.77] (-64.19, -5.39)
MMRM: Least Squares Mean Difference [SE] (95% CI)	49.45 [21.72] (6.21, 92.70)		
MMRM: P-value	0.026		
Corrected Hedges' g (95% CI)	0.488 (0.043, 0.932)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.086		
MPN0107 - Dizziness at Week 16			
n	67	83	
Mean (SD)	1.7 (2.14)	1.8 (2.28)	
Median	1.0	1.0	
Q1, Q3	0.0, 3.0	0.0, 3.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	78%	88%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	89%	91%	
Change in Dizziness at Week 16 from Baseline			
n	61	71	
Mean (SD)	-0.7 (2.90)	-0.2 (2.72)	
Median	0.0	0.0	
Q1, Q3	-2.0, 0.0	-1.0, 0.0	
Min, Max	-9.0, 9.0	-8.0, 8.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5907: Analysis of MPN-SAF Mean Questionnaire Item #7 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	73	76	
n [2]	61	71	
MMRM: Least Squares Mean [SE] (95% CI)	-0.40 [0.30] (-0.98, 0.19)	-0.34 [0.28] (-0.89, 0.21)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.06 [0.37] (-0.80, 0.68)		
MMRM: P-value	0.88		
Corrected Hedges' g (95% CI)	-0.025 (-0.367, 0.317)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.78		
Percent Change in Dizziness at Week 16 from Baseline			
n	34	43	
Mean (SD)	-5.9 (175.72)	-13.5 (108.90)	
Median	-50.0	-50.0	
Q1, Q3	-90.0, 0.0	-100.0, 0.0	
Min, Max	-100.0, 900.0	-100.0, 400.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	39	47	
n [2]	34	43	
MMRM: Least Squares Mean [SE] (95% CI)	6.41 [23.77] (-40.91, 53.72)	-15.65 [20.77] (-56.99, 25.70)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	22.05 [31.00] (-39.65, 83.76)		
MMRM: P-value	0.48		
Corrected Hedges' g (95% CI)	0.159 (-0.291, 0.610)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.85		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5907: Analysis of MPN-SAF Mean Questionnaire Item #7 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPN0107 - Dizziness at Week 20			
n	64	83	
Mean (SD)	2.0 (2.40)	1.3 (1.81)	
Median	1.0	1.0	
Q1, Q3	0.0, 3.0	0.0, 2.0	
Min, Max	0.0, 10.0	0.0, 9.0	
Return Rate (%)	74%	88%	
Number of Subjects in Risk	74	90	
Return Rate in Risk (%)	86%	92%	
Change in Dizziness at Week 20 from Baseline			
n	59	69	
Mean (SD)	-0.3 (2.53)	-0.5 (2.51)	
Median	0.0	0.0	
Q1, Q3	-1.0, 1.0	-2.0, 1.0	
Min, Max	-8.0, 9.0	-8.0, 6.0	
Difference in Change from Baseline at Week 20			
n [1]	73	76	
n [2]	59	69	
MMRM: Least Squares Mean [SE] (95% CI)	0.01 [0.27] (-0.53, 0.56)	-0.68 [0.25] (-1.19, -0.18)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.70 [0.34] (0.02, 1.37)		
MMRM: P-value	0.043		
Corrected Hedges' g (95% CI)	0.327 (-0.023, 0.677)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.37		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5907: Analysis of MPN-SAF Mean Questionnaire Item #7 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Dizziness at Week 20 from Baseline			
n	32	42	
Mean (SD)	37.6 (199.90)	-31.6 (86.03)	
Median	-8.3	-61.3	
Q1, Q3	-55.0, 25.0	-100.0, 0.0	
Min, Max	-100.0, 900.0	-100.0, 250.0	
Difference in Percent Change from Baseline at Week 20			
n [1]	39	47	
n [2]	32	42	
MMRM: Least Squares Mean [SE] (95% CI)	48.71 [23.88] (1.16, 96.26)	-34.29 [20.81] (-75.72, 7.15)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	83.00 [31.09] (21.10, 144.89)		
MMRM: P-value	0.009		
Corrected Hedges' g (95% CI)	0.608 (0.138, 1.079)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.070		
MPN0107 - Dizziness at Week 24			
n	65	82	
Mean (SD)	1.4 (2.10)	1.3 (1.85)	
Median	0.0	0.5	
Q1, Q3	0.0, 3.0	0.0, 2.0	
Min, Max	0.0, 9.0	0.0, 8.0	
Return Rate (%)	76%	87%	
Number of Subjects in Risk	70	87	
Return Rate in Risk (%)	93%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5907: Analysis of MPN-SAF Mean Questionnaire Item #7 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Dizziness at Week 24 from Baseline			
n	59	68	
Mean (SD)	-0.7 (3.03)	-0.6 (1.90)	
Median	0.0	0.0	
Q1, Q3	-3.0, 0.0	-1.0, 0.0	
Min, Max	-10.0, 9.0	-8.0, 4.0	
Difference in Change from Baseline at Week 24			
n [1]	73	76	
n [2]	59	68	
MMRM: Least Squares Mean [SE] (95% CI)	-0.38 [0.27] (-0.91, 0.15)	-0.76 [0.25] (-1.25, -0.27)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.38 [0.33] (-0.28, 1.03)		
MMRM: P-value	0.26		
Corrected Hedges' g (95% CI)	0.182 (-0.167, 0.532)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.90		
Percent Change in Dizziness at Week 24 from Baseline			
n	30	40	
Mean (SD)	-29.5 (113.30)	-37.6 (63.70)	
Median	-66.7	-50.0	
Q1, Q3	-100.0, -25.0	-100.0, 0.0	
Min, Max	-100.0, 400.0	-100.0, 133.3	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn07-db.pdf 29AUG2023: 9:38

Table 2.5907: Analysis of MPN-SAF Mean Questionnaire Item #7 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	39	47	
n [2]	30	40	
MMRM: Least Squares Mean [SE] (95% CI)	13.16 [21.46] (-29.57, 55.89)		-35.60 [18.60] (-72.63, 1.44)
MMRM: Least Squares Mean Difference [SE] (95% CI)	48.76 [27.76] (-6.50, 104.02)		
MMRM: P-value	0.083		
Corrected Hedges' g (95% CI)	0.410 (-0.068, 0.888)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.77		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5908: Analysis of MPN-SAF Mean Questionnaire Item #8 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
MPN0108 - Numbness at Baseline		
n	77	76
Mean (SD)	1.8 (2.36)	2.0 (2.65)
Median	1.0	1.0
Q1, Q3	0.0, 3.0	0.0, 3.0
Min, Max	0.0, 10.0	0.0, 9.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
MPN0108 - Numbness at Week 4		
n	76	90
Mean (SD)	1.8 (2.30)	1.6 (2.14)
Median	1.0	0.0
Q1, Q3	0.0, 3.0	0.0, 3.0
Min, Max	0.0, 8.0	0.0, 8.0
Return Rate (%)	88%	96%
Number of Subjects in Risk	82	94
Return Rate in Risk (%)	93%	96%
Change in Numbness at Week 4 from Baseline		
n	71	75
Mean (SD)	0.1 (2.12)	-0.4 (2.06)
Median	0.0	0.0
Q1, Q3	-1.0, 1.0	-1.0, 0.0
Min, Max	-5.0, 6.0	-7.0, 5.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5908: Analysis of MPN-SAF Mean Questionnaire Item #8 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	73	76	
n [2]	71	75	
MMRM: Least Squares Mean [SE] (95% CI)	0.18 [0.25] (-0.31, 0.66)	-0.17 [0.23] (-0.63, 0.29)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.35 [0.30] (-0.25, 0.95)		
MMRM: P-value	0.25		
Corrected Hedges' g (95% CI)	0.170 (-0.155, 0.495)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.19		
Percent Change in Numbness at Week 4 from Baseline			
n	40	41	
Mean (SD)	-11.0 (107.87)	-26.2 (86.04)	
Median	-22.5	-50.0	
Q1, Q3	-100.0, 0.0	-100.0, 0.0	
Min, Max	-100.0, 400.0	-100.0, 250.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	40	41	
n [2]	40	41	
MMRM: Least Squares Mean [SE] (95% CI)	5.35 [17.12] (-28.78, 39.47)	-6.63 [16.93] (-40.37, 27.11)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	11.97 [21.43] (-30.74, 54.69)		
MMRM: P-value	0.58		
Corrected Hedges' g (95% CI)	0.109 (-0.326, 0.545)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.55		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5908: Analysis of MPN-SAF Mean Questionnaire Item #8 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPN0108 - Numbness at Week 8			
n	70	86	
Mean (SD)	2.2 (2.72)	1.7 (2.05)	
Median	1.0	1.0	
Q1, Q3	0.0, 3.0	0.0, 3.0	
Min, Max	0.0, 10.0	0.0, 9.0	
Return Rate (%)	81%	91%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	91%	
Change in Numbness at Week 8 from Baseline			
n	65	73	
Mean (SD)	0.4 (2.95)	-0.2 (1.87)	
Median	0.0	0.0	
Q1, Q3	-1.0, 2.0	-1.0, 1.0	
Min, Max	-5.0, 9.0	-5.0, 5.0	
Difference in Change from Baseline at Week 8			
n [1]	73	76	
n [2]	65	73	
MMRM: Least Squares Mean [SE] (95% CI)	0.56 [0.28] (0.00, 1.11)	-0.03 [0.26] (-0.56, 0.49)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.59 [0.35] (-0.11, 1.29)		
MMRM: P-value	0.097		
Corrected Hedges' g (95% CI)	0.260 (-0.075, 0.596)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.36		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn08-db.pdf 29AUG2023: 9:39

Table 2.5908: Analysis of MPN-SAF Mean Questionnaire Item #8 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Numbness at Week 8 from Baseline		
n	38	39
Mean (SD)	21.1 (161.95)	-22.7 (66.55)
Median	-45.0	-40.0
Q1, Q3	-75.0, 100.0	-62.5, 0.0
Min, Max	-100.0, 700.0	-100.0, 150.0
Difference in Percent Change from Baseline at Week 8		
n [1]	40	41
n [2]	38	39
MMRM: Least Squares Mean [SE] (95% CI)	37.68 [21.06] (-4.29, 79.65)	-1.38 [20.71] (-42.65, 39.89)
MMRM: Least Squares Mean Difference [SE] (95% CI)	39.06 [27.40] (-15.54, 93.67)	
MMRM: P-value	0.16	
Corrected Hedges' g (95% CI)	0.298 (-0.151, 0.748)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.68	
MPN0108 - Numbness at Week 12		
n	71	89
Mean (SD)	2.1 (2.37)	1.6 (1.98)
Median	1.0	1.0
Q1, Q3	0.0, 3.0	0.0, 3.0
Min, Max	0.0, 9.0	0.0, 8.0
Return Rate (%)	83%	95%
Number of Subjects in Risk	76	94
Return Rate in Risk (%)	93%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5908: Analysis of MPN-SAF Mean Questionnaire Item #8 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Numbness at Week 12 from Baseline			
n	65	74	
Mean (SD)	0.3 (2.49)	-0.5 (2.06)	
Median	0.0	0.0	
Q1, Q3	-1.0, 1.0	-1.0, 0.0	
Min, Max	-5.0, 7.0	-8.0, 4.0	
Difference in Change from Baseline at Week 12			
n [1]	73	76	
n [2]	65	74	
MMRM: Least Squares Mean [SE] (95% CI)	0.37 [0.26] (-0.14, 0.88)	-0.29 [0.24] (-0.77, 0.18)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.66 [0.32] (0.03, 1.29)		
MMRM: P-value	0.039		
Corrected Hedges' g (95% CI)	0.318 (-0.017, 0.653)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.085		
Percent Change in Numbness at Week 12 from Baseline			
n	37	41	
Mean (SD)	12.4 (149.22)	-13.1 (82.67)	
Median	-33.3	-50.0	
Q1, Q3	-66.7, 20.0	-57.1, 0.0	
Min, Max	-100.0, 700.0	-100.0, 300.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5908: Analysis of MPN-SAF Mean Questionnaire Item #8 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	40	41	
n [2]	37	41	
MMRM: Least Squares Mean [SE] (95% CI)	23.81 [20.41] (-16.85, 64.48)		6.51 [19.77] (-32.89, 45.91)
MMRM: Least Squares Mean Difference [SE] (95% CI)	17.30 [26.21] (-34.94, 69.54)		
MMRM: P-value	0.51		
Corrected Hedges' g (95% CI)	0.137 (-0.308, 0.582)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.73		
MPN0108 - Numbness at Week 16			
n	67	83	
Mean (SD)	2.3 (2.53)	1.8 (2.17)	
Median	1.0	1.0	
Q1, Q3	0.0, 3.0	0.0, 3.0	
Min, Max	0.0, 8.0	0.0, 7.0	
Return Rate (%)	78%	88%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	89%	91%	
Change in Numbness at Week 16 from Baseline			
n	61	71	
Mean (SD)	0.5 (2.66)	-0.4 (2.08)	
Median	0.0	0.0	
Q1, Q3	-1.0, 1.0	-2.0, 1.0	
Min, Max	-5.0, 8.0	-5.0, 5.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5908: Analysis of MPN-SAF Mean Questionnaire Item #8 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Change from Baseline at Week 16		
n [1]	73	76
n [2]	61	71
MMRM: Least Squares Mean [SE] (95% CI)	0.48 [0.27] (-0.04, 1.01)	-0.28 [0.25] (-0.78, 0.21)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.77 [0.33] (0.11, 1.42)	
MMRM: P-value	0.022	
Corrected Hedges' g (95% CI)	0.365 (0.020, 0.710)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.11	
Percent Change in Numbness at Week 16 from Baseline		
n	35	38
Mean (SD)	15.4 (150.51)	-25.2 (85.36)
Median	-25.0	-50.0
Q1, Q3	-66.7, 40.0	-100.0, 0.0
Min, Max	-100.0, 700.0	-100.0, 250.0
Difference in Percent Change from Baseline at Week 16		
n [1]	40	41
n [2]	35	38
MMRM: Least Squares Mean [SE] (95% CI)	23.26 [20.42] (-17.44, 63.95)	-5.78 [19.85] (-45.35, 33.78)
MMRM: Least Squares Mean Difference [SE] (95% CI)	29.04 [26.28] (-23.33, 81.41)	
MMRM: P-value	0.27	
Corrected Hedges' g (95% CI)	0.236 (-0.225, 0.697)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.16	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn08-db.pdf 29AUG2023: 9:39

Table 2.5908: Analysis of MPN-SAF Mean Questionnaire Item #8 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPN0108 - Numbness at Week 20			
n	64	83	
Mean (SD)	2.4 (2.69)	1.6 (1.94)	
Median	1.0	1.0	
Q1, Q3	0.0, 4.0	0.0, 3.0	
Min, Max	0.0, 10.0	0.0, 8.0	
Return Rate (%)	74%	88%	
Number of Subjects in Risk	74	90	
Return Rate in Risk (%)	86%	92%	
Change in Numbness at Week 20 from Baseline			
n	59	69	
Mean (SD)	0.6 (3.16)	-0.6 (2.49)	
Median	0.0	0.0	
Q1, Q3	-1.0, 3.0	-2.0, 0.0	
Min, Max	-5.0, 9.0	-8.0, 7.0	
Difference in Change from Baseline at Week 20			
n [1]	73	76	
n [2]	59	69	
MMRM: Least Squares Mean [SE] (95% CI)	0.54 [0.30] (-0.06, 1.14)	-0.39 [0.28] (-0.95, 0.17)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.93 [0.38] (0.17, 1.69)		
MMRM: P-value	0.017		
Corrected Hedges' g (95% CI)	0.396 (0.045, 0.747)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.016		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn08-db.pdf 29AUG2023: 9:39

Table 2.5908: Analysis of MPN-SAF Mean Questionnaire Item #8 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Numbness at Week 20 from Baseline		
n	33	38
Mean (SD)	53.9 (212.56)	-10.6 (137.68)
Median	0.0	-50.0
Q1, Q3	-60.0, 75.0	-75.0, 0.0
Min, Max	-100.0, 800.0	-100.0, 700.0
Difference in Percent Change from Baseline at Week 20		
n [1]	40	41
n [2]	33	38
MMRM: Least Squares Mean [SE] (95% CI)	57.58 [29.08] (-0.37, 115.53)	14.72 [27.81] (-40.70, 70.13)
MMRM: Least Squares Mean Difference [SE] (95% CI)	42.87 [38.71] (-34.29, 120.02)	
MMRM: P-value	0.27	
Corrected Hedges' g (95% CI)	0.250 (-0.218, 0.718)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.060	
MPN0108 - Numbness at Week 24		
n	65	82
Mean (SD)	2.1 (2.35)	1.4 (1.84)
Median	1.0	0.5
Q1, Q3	0.0, 3.0	0.0, 2.0
Min, Max	0.0, 9.0	0.0, 7.0
Return Rate (%)	76%	87%
Number of Subjects in Risk	70	87
Return Rate in Risk (%)	93%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn08-db.pdf 29AUG2023: 9:39

Table 2.5908: Analysis of MPN-SAF Mean Questionnaire Item #8 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Change in Numbness at Week 24 from Baseline		
n	59	68
Mean (SD)	0.2 (2.71)	-0.5 (2.05)
Median	0.0	0.0
Q1, Q3	-2.0, 1.0	-1.0, 0.0
Min, Max	-6.0, 9.0	-6.0, 6.0
Difference in Change from Baseline at Week 24		
n [1]	73	76
n [2]	59	68
MMRM: Least Squares Mean [SE] (95% CI)	0.37 [0.27] (-0.16, 0.90)	-0.35 [0.25] (-0.85, 0.14)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.72 [0.33] (0.06, 1.38)	
MMRM: P-value	0.032	
Corrected Hedges' g (95% CI)	0.348 (-0.003, 0.700)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.16	
Percent Change in Numbness at Week 24 from Baseline		
n	32	35
Mean (SD)	15.2 (172.46)	-36.4 (61.90)
Median	-40.0	-50.0
Q1, Q3	-66.7, 30.0	-75.0, -25.0
Min, Max	-100.0, 800.0	-100.0, 100.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn08-db.pdf 29AUG2023: 9:39

Table 2.5908: Analysis of MPN-SAF Mean Questionnaire Item #8 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	40	41	
n [2]	32	35	
MMRM: Least Squares Mean [SE] (95% CI)	28.58 [22.05] (-15.36, 72.52)		-4.05 [21.35] (-46.60, 38.50)
MMRM: Least Squares Mean Difference [SE] (95% CI)	32.63 [28.68] (-24.53, 89.79)		
MMRM: P-value	0.26		
Corrected Hedges' g (95% CI)	0.257 (-0.224, 0.738)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.27		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5909: Analysis of MPN-SAF Mean Questionnaire Item #9 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
MPN0109 - Difficulty Sleep at Baseline		
n	77	76
Mean (SD)	3.7 (3.41)	3.5 (3.09)
Median	3.0	3.0
Q1, Q3	0.0, 7.0	1.0, 5.5
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
MPN0109 - Difficulty Sleep at Week 4		
n	76	90
Mean (SD)	2.9 (3.06)	2.8 (2.97)
Median	2.0	2.0
Q1, Q3	0.0, 4.5	0.0, 5.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	88%	96%
Number of Subjects in Risk	82	94
Return Rate in Risk (%)	93%	96%
Change in Difficulty Sleep at Week 4 from Baseline		
n	71	75
Mean (SD)	-0.8 (2.75)	-0.7 (2.00)
Median	0.0	0.0
Q1, Q3	-2.0, 1.0	-2.0, 1.0
Min, Max	-10.0, 6.0	-5.0, 4.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5909: Analysis of MPN-SAF Mean Questionnaire Item #9 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	73	76	
n [2]	71	75	
MMRM: Least Squares Mean [SE] (95% CI)	-0.45 [0.28] (-1.00, 0.10)	-0.53 [0.27] (-1.06, 0.00)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.08 [0.36] (-0.63, 0.78)		
MMRM: P-value	0.83		
Corrected Hedges' g (95% CI)	0.033 (-0.291, 0.358)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.72		
Percent Change in Difficulty Sleep at Week 4 from Baseline			
n	52	57	
Mean (SD)	-10.8 (91.97)	-28.3 (55.70)	
Median	-25.4	-30.0	
Q1, Q3	-81.7, 5.6	-71.4, 0.0	
Min, Max	-100.0, 300.0	-100.0, 100.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	53	58	
n [2]	52	57	
MMRM: Least Squares Mean [SE] (95% CI)	-4.19 [11.44] (-26.89, 18.50)	-26.72 [10.86] (-48.26, -5.18)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	22.53 [14.71] (-6.64, 51.70)		
MMRM: P-value	0.13		
Corrected Hedges' g (95% CI)	0.272 (-0.106, 0.650)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.37		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn09-db.pdf 29AUG2023: 9:39

Table 2.5909: Analysis of MPN-SAF Mean Questionnaire Item #9 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPN0109 - Difficulty Sleep at Week 8			
n	70	86	
Mean (SD)	2.8 (2.85)	2.3 (2.65)	
Median	2.0	1.0	
Q1, Q3	0.0, 5.0	0.0, 4.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	81%	91%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	91%	
Change in Difficulty Sleep at Week 8 from Baseline			
n	65	73	
Mean (SD)	-0.7 (2.08)	-1.1 (2.50)	
Median	0.0	-1.0	
Q1, Q3	-2.0, 0.0	-3.0, 0.0	
Min, Max	-7.0, 3.0	-7.0, 4.0	
Difference in Change from Baseline at Week 8			
n [1]	73	76	
n [2]	65	73	
MMRM: Least Squares Mean [SE] (95% CI)	-0.39 [0.27] (-0.92, 0.14)	-0.90 [0.25] (-1.40, -0.41)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.51 [0.34] (-0.15, 1.18)		
MMRM: P-value	0.13		
Corrected Hedges' g (95% CI)	0.238 (-0.097, 0.574)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.30		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5909: Analysis of MPN-SAF Mean Questionnaire Item #9 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Difficulty Sleep at Week 8 from Baseline		
n	48	56
Mean (SD)	-29.0 (51.30)	-30.2 (70.01)
Median	-23.6	-38.8
Q1, Q3	-75.7, 0.0	-93.8, 0.0
Min, Max	-100.0, 100.0	-100.0, 200.0
Difference in Percent Change from Baseline at Week 8		
n [1]	53	58
n [2]	48	56
MMRM: Least Squares Mean [SE] (95% CI)	-22.67 [9.84] (-42.19, -3.16)	-29.47 [9.18] (-47.68, -11.26)
MMRM: Least Squares Mean Difference [SE] (95% CI)	6.80 [12.18] (-17.36, 30.96)	
MMRM: P-value	0.58	
Corrected Hedges' g (95% CI)	0.099 (-0.287, 0.484)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.23	
MPN0109 - Difficulty Sleep at Week 12		
n	71	89
Mean (SD)	2.3 (2.53)	2.3 (2.77)
Median	2.0	1.0
Q1, Q3	0.0, 3.0	0.0, 4.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	83%	95%
Number of Subjects in Risk	76	94
Return Rate in Risk (%)	93%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5909: Analysis of MPN-SAF Mean Questionnaire Item #9 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Difficulty Sleep at Week 12 from Baseline			
n	65	74	
Mean (SD)	-1.0 (2.36)	-1.0 (2.46)	
Median	-1.0	-1.0	
Q1, Q3	-2.0, 0.0	-3.0, 0.0	
Min, Max	-8.0, 3.0	-8.0, 4.0	
Difference in Change from Baseline at Week 12			
n [1]	73	76	
n [2]	65	74	
MMRM: Least Squares Mean [SE] (95% CI)	-0.79 [0.26] (-1.31, -0.28)	-0.87 [0.24] (-1.35, -0.40)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.08 [0.32] (-0.56, 0.72)		
MMRM: P-value	0.81		
Corrected Hedges' g (95% CI)	0.038 (-0.295, 0.371)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.89		
Percent Change in Difficulty Sleep at Week 12 from Baseline			
n	46	56	
Mean (SD)	-34.6 (53.59)	-31.4 (73.63)	
Median	-38.8	-47.2	
Q1, Q3	-77.8, 0.0	-100.0, 0.0	
Min, Max	-100.0, 100.0	-100.0, 300.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5909: Analysis of MPN-SAF Mean Questionnaire Item #9 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	53	58	
n [2]	46	56	
MMRM: Least Squares Mean [SE] (95% CI)	-27.84 [10.33] (-48.32, -7.35)	-28.69 [9.53] (-47.60, -9.78)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.85 [12.84] (-24.61, 26.32)		
MMRM: P-value	0.95		
Corrected Hedges' g (95% CI)	0.012 (-0.378, 0.402)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.59		
MPN0109 - Difficulty Sleep at Week 16			
n	67	83	
Mean (SD)	2.6 (2.86)	2.5 (2.40)	
Median	2.0	2.0	
Q1, Q3	0.0, 4.0	0.0, 4.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	78%	88%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	89%	91%	
Change in Difficulty Sleep at Week 16 from Baseline			
n	61	71	
Mean (SD)	-0.9 (2.48)	-1.0 (2.71)	
Median	0.0	0.0	
Q1, Q3	-2.0, 0.0	-3.0, 1.0	
Min, Max	-8.0, 4.0	-8.0, 5.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5909: Analysis of MPN-SAF Mean Questionnaire Item #9 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	73	76	
n [2]	61	71	
MMRM: Least Squares Mean [SE] (95% CI)	-0.60 [0.28] (-1.15, -0.05)	-0.77 [0.26] (-1.28, -0.26)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.17 [0.35] (-0.52, 0.86)		
MMRM: P-value	0.63		
Corrected Hedges' g (95% CI)	0.077 (-0.266, 0.419)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.65		
Percent Change in Difficulty Sleep at Week 16 from Baseline			
n	44	53	
Mean (SD)	-27.9 (58.90)	-25.0 (68.10)	
Median	-35.4	-33.3	
Q1, Q3	-72.9, 0.0	-71.4, 0.0	
Min, Max	-100.0, 133.3	-100.0, 200.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	53	58	
n [2]	44	53	
MMRM: Least Squares Mean [SE] (95% CI)	-23.33 [10.16] (-43.47, -3.18)	-23.25 [9.41] (-41.92, -4.57)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.08 [12.61] (-25.08, 24.92)		
MMRM: P-value	0.99		
Corrected Hedges' g (95% CI)	-0.001 (-0.401, 0.399)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.67		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5909: Analysis of MPN-SAF Mean Questionnaire Item #9 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPN0109 - Difficulty Sleep at Week 20			
n	64	83	
Mean (SD)	2.6 (2.61)	2.5 (2.62)	
Median	2.0	2.0	
Q1, Q3	0.0, 4.0	0.0, 4.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	74%	88%	
Number of Subjects in Risk	74	90	
Return Rate in Risk (%)	86%	92%	
Change in Difficulty Sleep at Week 20 from Baseline			
n	59	69	
Mean (SD)	-1.0 (2.59)	-1.1 (2.65)	
Median	0.0	-1.0	
Q1, Q3	-2.0, 0.0	-3.0, 0.0	
Min, Max	-8.0, 4.0	-8.0, 6.0	
Difference in Change from Baseline at Week 20			
n [1]	73	76	
n [2]	59	69	
MMRM: Least Squares Mean [SE] (95% CI)	-0.67 [0.29] (-1.23, -0.10)	-0.94 [0.27] (-1.46, -0.41)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.27 [0.36] (-0.45, 0.99)		
MMRM: P-value	0.46		
Corrected Hedges' g (95% CI)	0.121 (-0.226, 0.469)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.55		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5909: Analysis of MPN-SAF Mean Questionnaire Item #9 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Difficulty Sleep at Week 20 from Baseline			
n	44	52	
Mean (SD)	-16.3 (87.59)	-34.6 (64.25)	
Median	-33.3	-50.0	
Q1, Q3	-61.3, 0.0	-81.7, 0.0	
Min, Max	-100.0, 400.0	-100.0, 166.7	
Difference in Percent Change from Baseline at Week 20			
n [1]	53	58	
n [2]	44	52	
MMRM: Least Squares Mean [SE] (95% CI)	-11.68 [11.91] (-35.31, 11.95)	-32.40 [11.07] (-54.37, -10.44)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	20.72 [15.21] (-9.45, 50.89)		
MMRM: P-value	0.18		
Corrected Hedges' g (95% CI)	0.259 (-0.145, 0.662)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.30		
MPN0109 - Difficulty Sleep at Week 24			
n	65	82	
Mean (SD)	2.0 (2.43)	2.1 (2.49)	
Median	1.0	1.0	
Q1, Q3	0.0, 3.0	0.0, 3.0	
Min, Max	0.0, 8.0	0.0, 10.0	
Return Rate (%)	76%	87%	
Number of Subjects in Risk	70	87	
Return Rate in Risk (%)	93%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5909: Analysis of MPN-SAF Mean Questionnaire Item #9 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Difficulty Sleep at Week 24 from Baseline			
n	59	68	
Mean (SD)	-1.4 (2.34)	-1.1 (3.09)	
Median	-1.0	-1.0	
Q1, Q3	-3.0, 0.0	-3.0, 1.0	
Min, Max	-8.0, 3.0	-9.0, 6.0	
Difference in Change from Baseline at Week 24			
n [1]	73	76	
n [2]	59	68	
MMRM: Least Squares Mean [SE] (95% CI)	-0.93 [0.29] (-1.51, -0.35)	-1.00 [0.27] (-1.54, -0.46)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.07 [0.37] (-0.67, 0.81)		
MMRM: P-value	0.85		
Corrected Hedges' g (95% CI)	0.030 (-0.318, 0.379)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.96		
Percent Change in Difficulty Sleep at Week 24 from Baseline			
n	42	50	
Mean (SD)	-39.5 (57.27)	-32.1 (80.86)	
Median	-37.5	-66.7	
Q1, Q3	-100.0, -12.5	-100.0, 0.0	
Min, Max	-100.0, 100.0	-100.0, 200.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.5909: Analysis of MPN-SAF Mean Questionnaire Item #9 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	53	58	
n [2]	42	50	
MMRM: Least Squares Mean [SE] (95% CI)	-28.51 [11.44] (-51.19, -5.83)		-28.45 [10.64] (-49.56, -7.35)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.06 [14.51] (-28.85, 28.72)		
MMRM: P-value	1.00		
Corrected Hedges' g (95% CI)	-0.001 (-0.411, 0.409)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.80		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5910: Analysis of MPN-SAF Mean Questionnaire Item #10 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
MPN0110 - Depression at Baseline		
n	77	76
Mean (SD)	2.7 (2.98)	2.0 (2.46)
Median	2.0	1.0
Q1, Q3	0.0, 5.0	0.0, 3.0
Min, Max	0.0, 10.0	0.0, 9.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
MPN0110 - Depression at Week 4		
n	76	90
Mean (SD)	1.8 (2.26)	1.6 (2.09)
Median	1.0	0.0
Q1, Q3	0.0, 3.0	0.0, 3.0
Min, Max	0.0, 10.0	0.0, 9.0
Return Rate (%)	88%	96%
Number of Subjects in Risk	82	94
Return Rate in Risk (%)	93%	96%
Change in Depression at Week 4 from Baseline		
n	71	75
Mean (SD)	-0.8 (2.33)	-0.5 (1.76)
Median	0.0	0.0
Q1, Q3	-2.0, 0.0	-1.0, 0.0
Min, Max	-7.0, 3.0	-5.0, 6.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn10-db.pdf 29AUG2023: 9:39

Table 2.5910: Analysis of MPN-SAF Mean Questionnaire Item #10 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	73	76	
n [2]	71	75	
MMRM: Least Squares Mean [SE] (95% CI)	-0.33 [0.22] (-0.76, 0.10)	-0.42 [0.21] (-0.83, -0.01)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.09 [0.27] (-0.45, 0.62)		
MMRM: P-value	0.75		
Corrected Hedges' g (95% CI)	0.048 (-0.276, 0.373)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.87		
Percent Change in Depression at Week 4 from Baseline			
n	46	43	
Mean (SD)	-20.6 (76.36)	-8.8 (94.61)	
Median	-45.0	-40.0	
Q1, Q3	-75.0, 16.7	-75.0, 14.3	
Min, Max	-100.0, 200.0	-100.0, 300.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	47	43	
n [2]	46	43	
MMRM: Least Squares Mean [SE] (95% CI)	-7.87 [13.00] (-33.74, 17.99)	-5.43 [13.28] (-31.83, 20.98)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.44 [17.66] (-37.57, 32.68)		
MMRM: P-value	0.89		
Corrected Hedges' g (95% CI)	-0.028 (-0.443, 0.388)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.73		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn10-db.pdf 29AUG2023: 9:39

Table 2.5910: Analysis of MPN-SAF Mean Questionnaire Item #10 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPN0110 - Depression at Week 8			
n	70	86	
Mean (SD)	1.6 (2.40)	1.5 (2.06)	
Median	0.0	1.0	
Q1, Q3	0.0, 2.0	0.0, 3.0	
Min, Max	0.0, 9.0	0.0, 8.0	
Return Rate (%)	81%	91%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	91%	
Change in Depression at Week 8 from Baseline			
n	65	73	
Mean (SD)	-0.8 (2.42)	-0.4 (2.00)	
Median	0.0	0.0	
Q1, Q3	-2.0, 0.0	-1.0, 0.0	
Min, Max	-9.0, 4.0	-6.0, 5.0	
Difference in Change from Baseline at Week 8			
n [1]	73	76	
n [2]	65	73	
MMRM: Least Squares Mean [SE] (95% CI)	-0.38 [0.24] (-0.85, 0.09)	-0.41 [0.22] (-0.85, 0.03)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.03 [0.30] (-0.56, 0.62)		
MMRM: P-value	0.92		
Corrected Hedges' g (95% CI)	0.016 (-0.318, 0.350)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.56		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn10-db.pdf 29AUG2023: 9:39

Table 2.5910: Analysis of MPN-SAF Mean Questionnaire Item #10 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Depression at Week 8 from Baseline			
n	41	41	
Mean (SD)	-35.8 (79.65)	-20.1 (84.76)	
Median	-50.0	-50.0	
Q1, Q3	-100.0, 0.0	-66.7, 0.0	
Min, Max	-100.0, 300.0	-100.0, 300.0	
Difference in Percent Change from Baseline at Week 8			
n [1]	47	43	
n [2]	41	41	
MMRM: Least Squares Mean [SE] (95% CI)	-20.69 [13.14] (-46.83, 5.46)	-17.80 [13.10] (-43.85, 8.25)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.89 [17.63] (-37.96, 32.19)		
MMRM: P-value	0.87		
Corrected Hedges' g (95% CI)	-0.034 (-0.467, 0.399)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.74		
MPN0110 - Depression at Week 12			
n	71	89	
Mean (SD)	1.9 (2.37)	1.6 (2.28)	
Median	1.0	1.0	
Q1, Q3	0.0, 3.0	0.0, 2.0	
Min, Max	0.0, 9.0	0.0, 9.0	
Return Rate (%)	83%	95%	
Number of Subjects in Risk	76	94	
Return Rate in Risk (%)	93%	95%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn10-db.pdf 29AUG2023: 9:39

Table 2.5910: Analysis of MPN-SAF Mean Questionnaire Item #10 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Depression at Week 12 from Baseline			
n	65	74	
Mean (SD)	-0.5 (2.49)	-0.4 (2.28)	
Median	0.0	0.0	
Q1, Q3	-1.0, 1.0	-1.0, 0.0	
Min, Max	-9.0, 6.0	-6.0, 7.0	
Difference in Change from Baseline at Week 12			
n [1]	73	76	
n [2]	65	74	
MMRM: Least Squares Mean [SE] (95% CI)	-0.10 [0.25] (-0.61, 0.40)	-0.32 [0.24] (-0.79, 0.15)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.22 [0.32] (-0.42, 0.86)		
MMRM: P-value	0.50		
Corrected Hedges' g (95% CI)	0.106 (-0.227, 0.440)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.65		
Percent Change in Depression at Week 12 from Baseline			
n	41	42	
Mean (SD)	-13.8 (89.72)	-12.1 (108.05)	
Median	-28.6	-46.4	
Q1, Q3	-80.0, 33.3	-75.0, 33.3	
Min, Max	-100.0, 300.0	-100.0, 500.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn10-db.pdf 29AUG2023: 9:39

Table 2.5910: Analysis of MPN-SAF Mean Questionnaire Item #10 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	47	43	
n [2]	41	42	
MMRM: Least Squares Mean [SE] (95% CI)	-4.36 [14.79] (-33.78, 25.07)		-7.46 [14.84] (-36.98, 22.06)
MMRM: Least Squares Mean Difference [SE] (95% CI)	3.10 [20.12] (-36.93, 43.13)		
MMRM: P-value	0.88		
Corrected Hedges' g (95% CI)	0.032 (-0.398, 0.463)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.59		
MPN0110 - Depression at Week 16			
n	67	83	
Mean (SD)	2.3 (2.74)	1.6 (2.26)	
Median	1.0	1.0	
Q1, Q3	0.0, 3.0	0.0, 2.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	78%	88%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	89%	91%	
Change in Depression at Week 16 from Baseline			
n	61	71	
Mean (SD)	-0.2 (2.19)	-0.4 (2.32)	
Median	0.0	0.0	
Q1, Q3	-1.0, 1.0	-2.0, 0.0	
Min, Max	-8.0, 6.0	-6.0, 6.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn10-db.pdf 29AUG2023: 9:39

Table 2.5910: Analysis of MPN-SAF Mean Questionnaire Item #10 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	73	76	
n [2]	61	71	
MMRM: Least Squares Mean [SE] (95% CI)	0.19 [0.27] (-0.34, 0.71)	-0.36 [0.25] (-0.85, 0.13)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.55 [0.34] (-0.12, 1.21)		
MMRM: P-value	0.11		
Corrected Hedges' g (95% CI)	0.262 (-0.082, 0.606)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.27		
Percent Change in Depression at Week 16 from Baseline			
n	39	39	
Mean (SD)	5.3 (87.37)	-29.0 (70.96)	
Median	0.0	-50.0	
Q1, Q3	-50.0, 40.0	-100.0, 0.0	
Min, Max	-100.0, 200.0	-100.0, 200.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	47	43	
n [2]	39	39	
MMRM: Least Squares Mean [SE] (95% CI)	13.13 [12.69] (-12.12, 38.39)	-27.34 [12.71] (-52.63, -2.05)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	40.47 [16.99] (6.68, 74.27)		
MMRM: P-value	0.020		
Corrected Hedges' g (95% CI)	0.505 (0.054, 0.956)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.015		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn10-db.pdf 29AUG2023: 9:39

Table 2.5910: Analysis of MPN-SAF Mean Questionnaire Item #10 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPN0110 - Depression at Week 20			
n	64	83	
Mean (SD)	1.9 (2.53)	1.5 (2.11)	
Median	1.0	1.0	
Q1, Q3	0.0, 3.0	0.0, 2.0	
Min, Max	0.0, 10.0	0.0, 9.0	
Return Rate (%)	74%	88%	
Number of Subjects in Risk	74	90	
Return Rate in Risk (%)	86%	92%	
Change in Depression at Week 20 from Baseline			
n	59	69	
Mean (SD)	-0.6 (2.37)	-0.6 (2.29)	
Median	0.0	0.0	
Q1, Q3	-1.0, 0.0	-1.0, 0.0	
Min, Max	-8.0, 5.0	-7.0, 6.0	
Difference in Change from Baseline at Week 20			
n [1]	73	76	
n [2]	59	69	
MMRM: Least Squares Mean [SE] (95% CI)	-0.24 [0.25] (-0.72, 0.25)		-0.49 [0.23] (-0.95, -0.04)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.26 [0.31] (-0.36, 0.87)		
MMRM: P-value	0.41		
Corrected Hedges' g (95% CI)	0.135 (-0.213, 0.483)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.74		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5910: Analysis of MPN-SAF Mean Questionnaire Item #10 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Depression at Week 20 from Baseline		
n	39	40
Mean (SD)	-25.7 (72.52)	-23.8 (91.55)
Median	-44.4	-46.4
Q1, Q3	-80.0, 0.0	-100.0, 0.0
Min, Max	-100.0, 250.0	-100.0, 300.0
Difference in Percent Change from Baseline at Week 20		
n [1]	47	43
n [2]	39	40
MMRM: Least Squares Mean [SE] (95% CI)	-17.97 [12.93] (-43.68, 7.75)	-21.84 [12.87] (-47.44, 3.75)
MMRM: Least Squares Mean Difference [SE] (95% CI)	3.87 [17.25] (-30.45, 38.20)	
MMRM: P-value	0.82	
Corrected Hedges' g (95% CI)	0.047 (-0.394, 0.488)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.72	
MPN0110 - Depression at Week 24		
n	65	82
Mean (SD)	1.6 (2.14)	1.5 (2.31)
Median	1.0	0.0
Q1, Q3	0.0, 3.0	0.0, 2.0
Min, Max	0.0, 8.0	0.0, 9.0
Return Rate (%)	76%	87%
Number of Subjects in Risk	70	87
Return Rate in Risk (%)	93%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5910: Analysis of MPN-SAF Mean Questionnaire Item #10 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Change in Depression at Week 24 from Baseline		
n	59	68
Mean (SD)	-0.8 (2.24)	-0.5 (2.56)
Median	0.0	0.0
Q1, Q3	-1.0, 0.0	-2.0, 0.0
Min, Max	-8.0, 7.0	-6.0, 9.0
Difference in Change from Baseline at Week 24		
n [1]	73	76
n [2]	59	68
MMRM: Least Squares Mean [SE] (95% CI)	-0.19 [0.27] (-0.72, 0.34)	-0.35 [0.25] (-0.85, 0.14)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.16 [0.34] (-0.52, 0.84)	
MMRM: P-value	0.64	
Corrected Hedges' g (95% CI)	0.077 (-0.272, 0.426)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.74	
Percent Change in Depression at Week 24 from Baseline		
n	37	37
Mean (SD)	-36.3 (62.54)	-35.1 (67.26)
Median	-50.0	-60.0
Q1, Q3	-88.9, 0.0	-100.0, 0.0
Min, Max	-100.0, 200.0	-100.0, 125.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5910: Analysis of MPN-SAF Mean Questionnaire Item #10 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	47	43	
n [2]	37	37	
MMRM: Least Squares Mean [SE] (95% CI)	-16.25 [12.17] (-40.46, 7.96)		-33.26 [12.19] (-57.50, -9.01)
MMRM: Least Squares Mean Difference [SE] (95% CI)	17.01 [16.16] (-15.14, 49.15)		
MMRM: P-value	0.30		
Corrected Hedges' g (95% CI)	0.227 (-0.230, 0.684)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.51		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.5911: Analysis of MPN-SAF Mean Questionnaire Item #11 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
MPN0111 - Sexual at Baseline		
n	77	76
Mean (SD)	2.6 (3.69)	2.4 (3.25)
Median	0.0	0.0
Q1, Q3	0.0, 5.0	0.0, 4.5
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
MPN0111 - Sexual at Week 4		
n	76	90
Mean (SD)	2.0 (2.95)	2.4 (3.49)
Median	0.0	0.0
Q1, Q3	0.0, 4.0	0.0, 5.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	88%	96%
Number of Subjects in Risk	82	94
Return Rate in Risk (%)	93%	96%
Change in Sexual at Week 4 from Baseline		
n	71	75
Mean (SD)	-0.3 (2.15)	0.1 (3.05)
Median	0.0	0.0
Q1, Q3	-1.0, 0.0	-1.0, 0.0
Min, Max	-5.0, 6.0	-7.0, 9.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn11-db.pdf 29AUG2023: 9:39

Table 2.5911: Analysis of MPN-SAF Mean Questionnaire Item #11 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	73	76	
n [2]	71	75	
MMRM: Least Squares Mean [SE] (95% CI)	0.03 [0.32] (-0.59, 0.66)	0.43 [0.30] (-0.16, 1.02)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.39 [0.39] (-1.16, 0.37)		
MMRM: P-value	0.31		
Corrected Hedges' g (95% CI)	-0.149 (-0.474, 0.176)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.91		
Percent Change in Sexual at Week 4 from Baseline			
n	31	37	
Mean (SD)	8.4 (113.62)	36.8 (236.59)	
Median	-30.0	-20.0	
Q1, Q3	-57.1, 33.3	-66.7, 0.0	
Min, Max	-100.0, 400.0	-100.0, 900.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	33	37	
n [2]	31	37	
MMRM: Least Squares Mean [SE] (95% CI)	18.89 [33.38] (-47.83, 85.62)	41.95 [30.87] (-19.75, 103.65)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-23.06 [44.24] (-111.49, 65.37)		
MMRM: P-value	0.60		
Corrected Hedges' g (95% CI)	-0.122 (-0.600, 0.356)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.45		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5911: Analysis of MPN-SAF Mean Questionnaire Item #11 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPN0111 - Sexual at Week 8			
n	70	86	
Mean (SD)	2.1 (3.00)	2.3 (3.38)	
Median	0.0	0.0	
Q1, Q3	0.0, 3.0	0.0, 4.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	81%	91%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	91%	
Change in Sexual at Week 8 from Baseline			
n	65	73	
Mean (SD)	-0.2 (2.11)	0.0 (3.38)	
Median	0.0	0.0	
Q1, Q3	0.0, 0.0	-1.0, 0.0	
Min, Max	-6.0, 5.0	-10.0, 9.0	
Difference in Change from Baseline at Week 8			
n [1]	73	76	
n [2]	65	73	
MMRM: Least Squares Mean [SE] (95% CI)		0.14 [0.34] (-0.53, 0.81)	0.27 [0.32] (-0.35, 0.90)
MMRM: Least Squares Mean Difference [SE] (95% CI)		-0.13 [0.42] (-0.96, 0.69)	
MMRM: P-value		0.75	
Corrected Hedges' g (95% CI)		-0.048 (-0.382, 0.286)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value		0.72	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5911: Analysis of MPN-SAF Mean Questionnaire Item #11 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Sexual at Week 8 from Baseline		
n	29	35
Mean (SD)	0.1 (76.64)	-1.9 (169.51)
Median	0.0	-33.3
Q1, Q3	-55.6, 33.3	-100.0, 25.0
Min, Max	-100.0, 200.0	-100.0, 900.0
Difference in Percent Change from Baseline at Week 8		
n [1]	33	37
n [2]	29	35
MMRM: Least Squares Mean [SE] (95% CI)	20.24 [25.95] (-31.63, 72.11)	-2.96 [23.47] (-49.87, 43.96)
MMRM: Least Squares Mean Difference [SE] (95% CI)	23.20 [33.37] (-43.51, 89.91)	
MMRM: P-value	0.49	
Corrected Hedges' g (95% CI)	0.165 (-0.328, 0.658)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.25	
MPN0111 - Sexual at Week 12		
n	71	89
Mean (SD)	2.2 (2.88)	2.4 (3.39)
Median	1.0	0.0
Q1, Q3	0.0, 4.0	0.0, 4.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	83%	95%
Number of Subjects in Risk	76	94
Return Rate in Risk (%)	93%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5911: Analysis of MPN-SAF Mean Questionnaire Item #11 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Change in Sexual at Week 12 from Baseline		
n	65	74
Mean (SD)	-0.1 (2.42)	0.1 (3.45)
Median	0.0	0.0
Q1, Q3	0.0, 1.0	-1.0, 0.0
Min, Max	-8.0, 6.0	-8.0, 9.0
Difference in Change from Baseline at Week 12		
n [1]	73	76
n [2]	65	74
MMRM: Least Squares Mean [SE] (95% CI)	0.24 [0.34] (-0.44, 0.92)	0.44 [0.32] (-0.20, 1.07)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.20 [0.43] (-1.04, 0.65)	
MMRM: P-value	0.65	
Corrected Hedges' g (95% CI)	-0.070 (-0.404, 0.263)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.68	
Percent Change in Sexual at Week 12 from Baseline		
n	29	36
Mean (SD)	31.9 (129.74)	5.1 (175.94)
Median	0.0	-35.4
Q1, Q3	-57.1, 66.7	-100.0, 5.6
Min, Max	-100.0, 400.0	-100.0, 900.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5911: Analysis of MPN-SAF Mean Questionnaire Item #11 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	33	37	
n [2]	29	36	
MMRM: Least Squares Mean [SE] (95% CI)	40.38 [27.26] (-14.11, 94.88)	10.18 [24.70] (-39.20, 59.56)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	30.20 [35.27] (-40.31, 100.70)		
MMRM: P-value	0.40		
Corrected Hedges' g (95% CI)	0.202 (-0.288, 0.692)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.19		
MPN0111 - Sexual at Week 16			
n	67	83	
Mean (SD)	2.1 (3.08)	2.5 (3.27)	
Median	0.0	1.0	
Q1, Q3	0.0, 3.0	0.0, 4.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	78%	88%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	89%	91%	
Change in Sexual at Week 16 from Baseline			
n	61	71	
Mean (SD)	-0.3 (2.54)	0.1 (3.35)	
Median	0.0	0.0	
Q1, Q3	0.0, 0.0	-1.0, 1.0	
Min, Max	-8.0, 7.0	-8.0, 9.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5911: Analysis of MPN-SAF Mean Questionnaire Item #11 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	73	76	
n [2]	61	71	
MMRM: Least Squares Mean [SE] (95% CI)	0.14 [0.36] (-0.58, 0.86)	0.59 [0.34] (-0.08, 1.26)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.45 [0.45] (-1.34, 0.45)		
MMRM: P-value	0.33		
Corrected Hedges' g (95% CI)	-0.157 (-0.499, 0.186)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.77		
Percent Change in Sexual at Week 16 from Baseline			
n	29	33	
Mean (SD)	20.6 (128.69)	7.7 (148.67)	
Median	0.0	-25.0	
Q1, Q3	-50.0, 33.3	-75.0, 33.3	
Min, Max	-100.0, 500.0	-100.0, 700.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	33	37	
n [2]	29	33	
MMRM: Least Squares Mean [SE] (95% CI)	30.01 [30.19] (-30.33, 90.36)	45.70 [28.02] (-10.31, 101.71)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-15.69 [39.81] (-95.27, 63.89)		
MMRM: P-value	0.69		
Corrected Hedges' g (95% CI)	-0.096 (-0.595, 0.403)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.30		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5911: Analysis of MPN-SAF Mean Questionnaire Item #11 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPN0111 - Sexual at Week 20			
n	64	83	
Mean (SD)	2.3 (3.24)	2.3 (3.30)	
Median	0.0	0.0	
Q1, Q3	0.0, 3.5	0.0, 3.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	74%	88%	
Number of Subjects in Risk	74	90	
Return Rate in Risk (%)	86%	92%	
Change in Sexual at Week 20 from Baseline			
n	59	69	
Mean (SD)	-0.1 (2.66)	0.2 (3.66)	
Median	0.0	0.0	
Q1, Q3	-1.0, 0.0	-1.0, 1.0	
Min, Max	-7.0, 10.0	-8.0, 10.0	
Difference in Change from Baseline at Week 20			
n [1]	73	76	
n [2]	59	69	
MMRM: Least Squares Mean [SE] (95% CI)		0.27 [0.38] (-0.48, 1.02)	0.65 [0.35] (-0.04, 1.35)
MMRM: Least Squares Mean Difference [SE] (95% CI)		-0.39 [0.48] (-1.33, 0.56)	
MMRM: P-value	0.42		
Corrected Hedges' g (95% CI)	-0.131 (-0.479, 0.216)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.77		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5911: Analysis of MPN-SAF Mean Questionnaire Item #11 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Sexual at Week 20 from Baseline			
n	27	32	
Mean (SD)	1.3 (98.58)	-26.2 (81.39)	
Median	-20.0	-31.7	
Q1, Q3	-70.0, 33.3	-100.0, 0.0	
Min, Max	-100.0, 300.0	-100.0, 300.0	
Difference in Percent Change from Baseline at Week 20			
n [1]	33	37	
n [2]	27	32	
MMRM: Least Squares Mean [SE] (95% CI)	8.03 [23.19] (-38.33, 54.39)	6.19 [21.31] (-36.41, 48.78)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.84 [29.69] (-57.50, 61.19)		
MMRM: P-value	0.95		
Corrected Hedges' g (95% CI)	0.015 (-0.497, 0.527)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.14		
MPN0111 - Sexual at Week 24			
n	65	82	
Mean (SD)	1.9 (2.70)	2.5 (3.28)	
Median	0.0	1.0	
Q1, Q3	0.0, 3.0	0.0, 4.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	76%	87%	
Number of Subjects in Risk	70	87	
Return Rate in Risk (%)	93%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5911: Analysis of MPN-SAF Mean Questionnaire Item #11 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Change in Sexual at Week 24 from Baseline		
n	59	68
Mean (SD)	-0.4 (2.58)	0.2 (2.81)
Median	0.0	0.0
Q1, Q3	0.0, 0.0	-1.0, 1.0
Min, Max	-9.0, 4.0	-8.0, 10.0
Difference in Change from Baseline at Week 24		
n [1]	73	76
n [2]	59	68
MMRM: Least Squares Mean [SE] (95% CI)	-0.10 [0.34] (-0.77, 0.56)	0.82 [0.32] (0.20, 1.45)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.93 [0.42] (-1.75, -0.10)	
MMRM: P-value	0.027	
Corrected Hedges' g (95% CI)	-0.355 (-0.706, -0.003)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.63	
Percent Change in Sexual at Week 24 from Baseline		
n	25	31
Mean (SD)	20.7 (128.45)	-18.4 (61.75)
Median	-20.0	-25.0
Q1, Q3	-66.7, 66.7	-80.0, 16.7
Min, Max	-100.0, 400.0	-100.0, 100.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn11-db.pdf 29AUG2023: 9:39

Table 2.5911: Analysis of MPN-SAF Mean Questionnaire Item #11 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	33	37	
n [2]	25	31	
MMRM: Least Squares Mean [SE] (95% CI)	18.65 [26.67] (-34.66, 71.95)		31.68 [24.45] (-17.20, 80.56)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-13.04 [34.67] (-82.33, 56.26)		
MMRM: P-value	0.71		
Corrected Hedges' g (95% CI)	-0.095 (-0.622, 0.432)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.67		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.5912: Analysis of MPN-SAF Mean Questionnaire Item #12 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
MPN0112 - Cough at Baseline		
n	77	76
Mean (SD)	1.7 (2.69)	1.9 (2.42)
Median	0.0	1.0
Q1, Q3	0.0, 2.0	0.0, 3.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
MPN0112 - Cough at Week 4		
n	76	90
Mean (SD)	1.8 (2.42)	1.0 (1.74)
Median	1.0	0.0
Q1, Q3	0.0, 3.0	0.0, 1.0
Min, Max	0.0, 10.0	0.0, 8.0
Return Rate (%)	88%	96%
Number of Subjects in Risk	82	94
Return Rate in Risk (%)	93%	96%
Change in Cough at Week 4 from Baseline		
n	71	75
Mean (SD)	-0.1 (2.79)	-1.0 (2.29)
Median	0.0	0.0
Q1, Q3	-1.0, 1.0	-2.0, 0.0
Min, Max	-8.0, 7.0	-8.0, 4.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn12-db.pdf 29AUG2023: 9:39

Table 2.5912: Analysis of MPN-SAF Mean Questionnaire Item #12 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	73	76	
n [2]	71	75	
MMRM: Least Squares Mean [SE] (95% CI)	0.50 [0.24] (0.02, 0.98)	-0.38 [0.23] (-0.84, 0.08)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.88 [0.30] (0.28, 1.48)		
MMRM: P-value	0.004		
Corrected Hedges' g (95% CI)	0.431 (0.103, 0.759)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.037		
Percent Change in Cough at Week 4 from Baseline			
n	37	43	
Mean (SD)	18.8 (172.58)	-44.7 (97.00)	
Median	-50.0	-83.3	
Q1, Q3	-100.0, 66.7	-100.0, -25.0	
Min, Max	-100.0, 600.0	-100.0, 400.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	37	44	
n [2]	37	43	
MMRM: Least Squares Mean [SE] (95% CI)	47.60 [24.57] (-1.37, 96.57)	-37.33 [21.50] (-80.18, 5.53)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	84.93 [30.85] (23.45, 146.41)		
MMRM: P-value	0.007		
Corrected Hedges' g (95% CI)	0.580 (0.132, 1.029)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.007		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5912: Analysis of MPN-SAF Mean Questionnaire Item #12 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPN0112 - Cough at Week 8			
n	70	86	
Mean (SD)	2.1 (2.71)	1.2 (1.86)	
Median	1.0	0.0	
Q1, Q3	0.0, 3.0	0.0, 2.0	
Min, Max	0.0, 10.0	0.0, 8.0	
Return Rate (%)	81%	91%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	91%	
Change in Cough at Week 8 from Baseline			
n	65	73	
Mean (SD)	0.3 (2.98)	-0.7 (2.59)	
Median	0.0	0.0	
Q1, Q3	-1.0, 1.0	-2.0, 0.0	
Min, Max	-7.0, 8.0	-9.0, 6.0	
Difference in Change from Baseline at Week 8			
n [1]	73	76	
n [2]	65	73	
MMRM: Least Squares Mean [SE] (95% CI)	1.01 [0.29] (0.44, 1.59)	-0.19 [0.28] (-0.73, 0.36)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.20 [0.37] (0.46, 1.93)		
MMRM: P-value	0.002		
Corrected Hedges' g (95% CI)	0.507 (0.168, 0.847)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.091		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5912: Analysis of MPN-SAF Mean Questionnaire Item #12 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Cough at Week 8 from Baseline		
n	33	41
Mean (SD)	73.7 (241.95)	-22.8 (127.60)
Median	-33.3	-83.3
Q1, Q3	-66.7, 100.0	-100.0, 0.0
Min, Max	-100.0, 800.0	-100.0, 400.0
Difference in Percent Change from Baseline at Week 8		
n [1]	37	44
n [2]	33	41
MMRM: Least Squares Mean [SE] (95% CI)	114.89 [33.16] (48.81, 180.97)	-18.40 [29.24] (-76.68, 39.88)
MMRM: Least Squares Mean Difference [SE] (95% CI)	133.29 [42.89] (47.81, 218.77)	
MMRM: P-value	0.003	
Corrected Hedges' g (95% CI)	0.699 (0.227, 1.171)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.034	
MPN0112 - Cough at Week 12		
n	71	89
Mean (SD)	2.0 (2.61)	0.9 (1.51)
Median	1.0	0.0
Q1, Q3	0.0, 3.0	0.0, 1.0
Min, Max	0.0, 10.0	0.0, 8.0
Return Rate (%)	83%	95%
Number of Subjects in Risk	76	94
Return Rate in Risk (%)	93%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn12-db.pdf 29AUG2023: 9:39

Table 2.5912: Analysis of MPN-SAF Mean Questionnaire Item #12 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Cough at Week 12 from Baseline			
n	65	74	
Mean (SD)	0.4 (3.03)	-0.9 (2.54)	
Median	0.0	0.0	
Q1, Q3	-1.0, 2.0	-2.0, 0.0	
Min, Max	-9.0, 7.0	-10.0, 8.0	
Difference in Change from Baseline at Week 12			
n [1]	73	76	
n [2]	65	74	
MMRM: Least Squares Mean [SE] (95% CI)	0.91 [0.28] (0.36, 1.46)	-0.28 [0.26] (-0.79, 0.23)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.19 [0.35] (0.50, 1.88)		
MMRM: P-value	< 0.001		
Corrected Hedges' g (95% CI)	0.531 (0.192, 0.870)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.004		
Percent Change in Cough at Week 12 from Baseline			
n	31	43	
Mean (SD)	52.8 (181.20)	-38.4 (107.16)	
Median	-16.7	-87.5	
Q1, Q3	-80.0, 100.0	-100.0, -25.0	
Min, Max	-100.0, 600.0	-100.0, 300.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5912: Analysis of MPN-SAF Mean Questionnaire Item #12 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	37	44	
n [2]	31	43	
MMRM: Least Squares Mean [SE] (95% CI)	85.93 [26.13] (33.84, 138.01)		-29.98 [22.33] (-74.47, 14.52)
MMRM: Least Squares Mean Difference [SE] (95% CI)	115.90 [32.64] (50.86, 180.95)		
MMRM: P-value	< 0.001		
Corrected Hedges' g (95% CI)	0.785 (0.307, 1.264)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.002		
MPN0112 - Cough at Week 16			
n	67	83	
Mean (SD)	2.3 (2.72)	1.4 (2.22)	
Median	1.0	0.0	
Q1, Q3	0.0, 4.0	0.0, 2.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	78%	88%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	89%	91%	
Change in Cough at Week 16 from Baseline			
n	61	71	
Mean (SD)	0.8 (3.37)	-0.4 (2.46)	
Median	0.0	0.0	
Q1, Q3	0.0, 3.0	-2.0, 1.0	
Min, Max	-9.0, 9.0	-10.0, 6.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn12-db.pdf 29AUG2023: 9:39

Table 2.5912: Analysis of MPN-SAF Mean Questionnaire Item #12 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Change from Baseline at Week 16		
n [1]	73	76
n [2]	61	71
MMRM: Least Squares Mean [SE] (95% CI)	1.24 [0.31] (0.62, 1.85)	0.23 [0.29] (-0.35, 0.80)
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.01 [0.40] (0.22, 1.80)	
MMRM: P-value	0.013	
Corrected Hedges' g (95% CI)	0.410 (0.064, 0.756)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.022	
Percent Change in Cough at Week 16 from Baseline		
n	29	41
Mean (SD)	80.8 (204.86)	-22.8 (102.31)
Median	0.0	-75.0
Q1, Q3	-90.0, 200.0	-100.0, 0.0
Min, Max	-100.0, 600.0	-100.0, 250.0
Difference in Percent Change from Baseline at Week 16		
n [1]	37	44
n [2]	29	41
MMRM: Least Squares Mean [SE] (95% CI)	110.17 [28.21] (53.94, 166.39)	-8.52 [23.95] (-56.26, 39.21)
MMRM: Least Squares Mean Difference [SE] (95% CI)	118.69 [35.40] (48.13, 189.25)	
MMRM: P-value	0.001	
Corrected Hedges' g (95% CI)	0.768 (0.276, 1.261)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.004	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn12-db.pdf 29AUG2023: 9:39

Table 2.5912: Analysis of MPN-SAF Mean Questionnaire Item #12 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
MPN0112 - Cough at Week 20		
n	64	83
Mean (SD)	1.8 (2.57)	1.3 (2.18)
Median	0.5	0.0
Q1, Q3	0.0, 3.0	0.0, 1.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	74%	88%
Number of Subjects in Risk	74	90
Return Rate in Risk (%)	86%	92%
Change in Cough at Week 20 from Baseline		
n	59	69
Mean (SD)	0.1 (2.84)	-0.6 (2.25)
Median	0.0	0.0
Q1, Q3	-1.0, 2.0	-2.0, 0.0
Min, Max	-9.0, 6.0	-10.0, 5.0
Difference in Change from Baseline at Week 20		
n [1]	73	76
n [2]	59	69
MMRM: Least Squares Mean [SE] (95% CI)	0.65 [0.28] (0.10, 1.19)	0.02 [0.26] (-0.49, 0.53)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.63 [0.35] (-0.06, 1.31)	
MMRM: P-value	0.072	
Corrected Hedges' g (95% CI)	0.294 (-0.056, 0.643)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.22	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5912: Analysis of MPN-SAF Mean Questionnaire Item #12 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Cough at Week 20 from Baseline			
n	28	39	
Mean (SD)	12.0 (160.33)	-33.8 (85.09)	
Median	-58.3	-50.0	
Q1, Q3	-100.0, 50.0	-100.0, 0.0	
Min, Max	-100.0, 500.0	-100.0, 300.0	
Difference in Percent Change from Baseline at Week 20			
n [1]	37	44	
n [2]	28	39	
MMRM: Least Squares Mean [SE] (95% CI)	53.55 [23.93] (5.85, 101.26)	-19.44 [20.48] (-60.26, 21.37)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	73.00 [29.59] (14.02, 131.98)		
MMRM: P-value	0.016		
Corrected Hedges' g (95% CI)	0.566 (0.072, 1.061)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.30		
MPN0112 - Cough at Week 24			
n	65	82	
Mean (SD)	1.7 (2.02)	1.0 (1.82)	
Median	1.0	0.0	
Q1, Q3	0.0, 3.0	0.0, 1.0	
Min, Max	0.0, 9.0	0.0, 10.0	
Return Rate (%)	76%	87%	
Number of Subjects in Risk	70	87	
Return Rate in Risk (%)	93%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5912: Analysis of MPN-SAF Mean Questionnaire Item #12 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Cough at Week 24 from Baseline			
n	59	68	
Mean (SD)	0.0 (2.93)	-0.9 (2.31)	
Median	0.0	0.0	
Q1, Q3	-1.0, 1.0	-2.0, 0.0	
Min, Max	-9.0, 7.0	-10.0, 4.0	
Difference in Change from Baseline at Week 24			
n [1]	73	76	
n [2]	59	68	
MMRM: Least Squares Mean [SE] (95% CI)	0.66 [0.25] (0.16, 1.16)	-0.22 [0.24] (-0.69, 0.25)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.88 [0.31] (0.26, 1.50)		
MMRM: P-value	0.006		
Corrected Hedges' g (95% CI)	0.446 (0.093, 0.799)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.023		
Percent Change in Cough at Week 24 from Baseline			
n	28	38	
Mean (SD)	9.3 (147.61)	-49.9 (79.45)	
Median	-50.0	-91.7	
Q1, Q3	-95.0, 50.0	-100.0, -12.5	
Min, Max	-100.0, 500.0	-100.0, 300.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

GSK Oncology
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Table 2.5912: Analysis of MPN-SAF Mean Questionnaire Item #12 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	37	44	
n [2]	28	38	
MMRM: Least Squares Mean [SE] (95% CI)	68.04 [25.41] (17.40, 118.68)	-27.92 [21.90] (-71.57, 15.74)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	95.96 [31.72] (32.73, 159.18)		
MMRM: P-value	0.003		
Corrected Hedges' g (95% CI)	0.704 (0.201, 1.206)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.056		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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GSK Oncology
Study GS-US-352-0101

Table 2.5913: Analysis of MPN-SAF Mean Questionnaire Item #13 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
MPN0113 - Night Sweats at Baseline		
n	77	76
Mean (SD)	2.9 (3.16)	3.0 (2.79)
Median	2.0	2.0
Q1, Q3	0.0, 5.0	1.0, 5.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
MPN0113 - Night Sweats at Week 4		
n	76	90
Mean (SD)	1.5 (2.13)	1.4 (1.94)
Median	1.0	1.0
Q1, Q3	0.0, 2.0	0.0, 2.0
Min, Max	0.0, 10.0	0.0, 9.0
Return Rate (%)	88%	96%
Number of Subjects in Risk	82	94
Return Rate in Risk (%)	93%	96%
Change in Night Sweats at Week 4 from Baseline		
n	71	75
Mean (SD)	-1.3 (2.58)	-1.6 (2.35)
Median	0.0	-1.0
Q1, Q3	-2.0, 0.0	-3.0, 0.0
Min, Max	-10.0, 4.0	-9.0, 2.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5913: Analysis of MPN-SAF Mean Questionnaire Item #13 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	73	76	
n [2]	71	75	
MMRM: Least Squares Mean [SE] (95% CI)	-1.21 [0.23] (-1.66, -0.75)	-1.46 [0.22] (-1.90, -1.03)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.26 [0.28] (-0.30, 0.82)		
MMRM: P-value	0.37		
Corrected Hedges' g (95% CI)	0.133 (-0.192, 0.457)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.51		
Percent Change in Night Sweats at Week 4 from Baseline			
n	47	57	
Mean (SD)	-37.5 (67.64)	-54.0 (49.10)	
Median	-60.0	-66.7	
Q1, Q3	-85.7, 0.0	-100.0, -25.0	
Min, Max	-100.0, 200.0	-100.0, 66.7	
Difference in Percent Change from Baseline at Week 4			
n [1]	48	58	
n [2]	47	57	
MMRM: Least Squares Mean [SE] (95% CI)	-34.48 [9.38] (-53.09, -15.86)	-53.13 [8.55] (-70.11, -36.16)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	18.66 [11.48] (-4.13, 41.44)		
MMRM: P-value	0.11		
Corrected Hedges' g (95% CI)	0.287 (-0.101, 0.675)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.12		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn13-db.pdf 29AUG2023: 9:39

Table 2.5913: Analysis of MPN-SAF Mean Questionnaire Item #13 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPN0113 - Night Sweats at Week 8			
n	70	86	
Mean (SD)	1.9 (2.58)	1.3 (2.10)	
Median	1.0	0.0	
Q1, Q3	0.0, 3.0	0.0, 2.0	
Min, Max	0.0, 10.0	0.0, 9.0	
Return Rate (%)	81%	91%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	91%	
Change in Night Sweats at Week 8 from Baseline			
n	65	73	
Mean (SD)	-0.9 (2.64)	-1.7 (2.27)	
Median	0.0	-1.0	
Q1, Q3	-2.0, 0.0	-3.0, 0.0	
Min, Max	-9.0, 6.0	-8.0, 2.0	
Difference in Change from Baseline at Week 8			
n [1]	73	76	
n [2]	65	73	
MMRM: Least Squares Mean [SE] (95% CI)	-0.85 [0.26] (-1.36, -0.34)	-1.61 [0.24] (-2.09, -1.13)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.76 [0.33] (0.12, 1.41)		
MMRM: P-value	0.021		
Corrected Hedges' g (95% CI)	0.362 (0.025, 0.699)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.054		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn13-db.pdf 29AUG2023: 9:39

Table 2.5913: Analysis of MPN-SAF Mean Questionnaire Item #13 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Night Sweats at Week 8 from Baseline			
n	43	55	
Mean (SD)	-35.0 (65.78)	-58.8 (46.08)	
Median	-50.0	-75.0	
Q1, Q3	-100.0, 0.0	-100.0, 0.0	
Min, Max	-100.0, 200.0	-100.0, 50.0	
Difference in Percent Change from Baseline at Week 8			
n [1]	48	58	
n [2]	43	55	
MMRM: Least Squares Mean [SE] (95% CI)	-34.76 [9.29] (-53.19, -16.33)	-58.37 [8.38] (-74.99, -41.74)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	23.61 [11.28] (1.23, 45.99)		
MMRM: P-value	0.039		
Corrected Hedges' g (95% CI)	0.380 (-0.022, 0.783)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.084		
MPN0113 - Night Sweats at Week 12			
n	71	89	
Mean (SD)	1.5 (2.13)	1.3 (1.90)	
Median	1.0	0.0	
Q1, Q3	0.0, 2.0	0.0, 2.0	
Min, Max	0.0, 10.0	0.0, 7.0	
Return Rate (%)	83%	95%	
Number of Subjects in Risk	76	94	
Return Rate in Risk (%)	93%	95%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5913: Analysis of MPN-SAF Mean Questionnaire Item #13 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Change in Night Sweats at Week 12 from Baseline		
n	65	74
Mean (SD)	-1.4 (3.06)	-1.7 (2.18)
Median	0.0	-1.0
Q1, Q3	-3.0, 0.0	-3.0, 0.0
Min, Max	-10.0, 8.0	-7.0, 3.0
Difference in Change from Baseline at Week 12		
n [1]	73	76
n [2]	65	74
MMRM: Least Squares Mean [SE] (95% CI)	-1.24 [0.24] (-1.71, -0.77)	-1.62 [0.22] (-2.07, -1.18)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.39 [0.29] (-0.19, 0.97)	
MMRM: P-value	0.19	
Corrected Hedges' g (95% CI)	0.200 (-0.134, 0.534)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.14	
Percent Change in Night Sweats at Week 12 from Baseline		
n	43	56
Mean (SD)	-42.3 (63.39)	-64.1 (42.08)
Median	-66.7	-82.9
Q1, Q3	-100.0, 0.0	-100.0, -33.8
Min, Max	-100.0, 150.0	-100.0, 50.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn13-db.pdf 29AUG2023: 9:39

Table 2.5913: Analysis of MPN-SAF Mean Questionnaire Item #13 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	48	58	
n [2]	43	56	
MMRM: Least Squares Mean [SE] (95% CI)	-39.75 [8.82] (-57.25, -22.25)		-63.98 [7.93] (-79.72, -48.23)
MMRM: Least Squares Mean Difference [SE] (95% CI)	24.23 [10.55] (3.29, 45.17)		
MMRM: P-value	0.024		
Corrected Hedges' g (95% CI)	0.410 (0.008, 0.811)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.071		
MPN0113 - Night Sweats at Week 16			
n	67	83	
Mean (SD)	1.7 (2.35)	1.6 (2.12)	
Median	1.0	0.0	
Q1, Q3	0.0, 3.0	0.0, 3.0	
Min, Max	0.0, 10.0	0.0, 8.0	
Return Rate (%)	78%	88%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	89%	91%	
Change in Night Sweats at Week 16 from Baseline			
n	61	71	
Mean (SD)	-1.1 (2.86)	-1.6 (2.56)	
Median	-1.0	-1.0	
Q1, Q3	-2.0, 0.0	-3.0, 0.0	
Min, Max	-9.0, 6.0	-8.0, 5.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5913: Analysis of MPN-SAF Mean Questionnaire Item #13 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	73	76	
n [2]	61	71	
MMRM: Least Squares Mean [SE] (95% CI)	-1.05 [0.26] (-1.57, -0.54)	-1.44 [0.24] (-1.92, -0.96)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.39 [0.33] (-0.25, 1.03)		
MMRM: P-value	0.23		
Corrected Hedges' g (95% CI)	0.189 (-0.154, 0.532)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.30		
Percent Change in Night Sweats at Week 16 from Baseline			
n	41	53	
Mean (SD)	-22.9 (110.68)	-55.8 (66.52)	
Median	-50.0	-75.0	
Q1, Q3	-90.0, -10.0	-100.0, -33.3	
Min, Max	-100.0, 500.0	-100.0, 300.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	48	58	
n [2]	41	53	
MMRM: Least Squares Mean [SE] (95% CI)	-23.37 [13.87] (-50.88, 4.15)	-56.71 [12.36] (-81.24, -32.17)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	33.34 [17.77] (-1.92, 68.60)		
MMRM: P-value	0.064		
Corrected Hedges' g (95% CI)	0.370 (-0.042, 0.781)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.16		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5913: Analysis of MPN-SAF Mean Questionnaire Item #13 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPN0113 - Night Sweats at Week 20			
n	64	83	
Mean (SD)	1.7 (2.61)	1.4 (2.01)	
Median	0.0	0.0	
Q1, Q3	0.0, 2.0	0.0, 2.0	
Min, Max	0.0, 10.0	0.0, 8.0	
Return Rate (%)	74%	88%	
Number of Subjects in Risk	74	90	
Return Rate in Risk (%)	86%	92%	
Change in Night Sweats at Week 20 from Baseline			
n	59	69	
Mean (SD)	-1.1 (3.31)	-1.7 (2.61)	
Median	-1.0	-2.0	
Q1, Q3	-3.0, 0.0	-3.0, 0.0	
Min, Max	-9.0, 10.0	-8.0, 7.0	
Difference in Change from Baseline at Week 20			
n [1]	73	76	
n [2]	59	69	
MMRM: Least Squares Mean [SE] (95% CI)	-1.10 [0.29] (-1.67, -0.53)	-1.54 [0.27] (-2.07, -1.00)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.44 [0.37] (-0.29, 1.16)		
MMRM: P-value	0.24		
Corrected Hedges' g (95% CI)	0.195 (-0.153, 0.543)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.18		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn13-db.pdf 29AUG2023: 9:39

Table 2.5913: Analysis of MPN-SAF Mean Questionnaire Item #13 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Night Sweats at Week 20 from Baseline			
n	38	51	
Mean (SD)	-40.8 (100.66)	-67.9 (39.81)	
Median	-72.2	-75.0	
Q1, Q3	-100.0, -20.0	-100.0, -50.0	
Min, Max	-100.0, 400.0	-100.0, 50.0	
Difference in Percent Change from Baseline at Week 20			
n [1]	48	58	
n [2]	38	51	
MMRM: Least Squares Mean [SE] (95% CI)	-37.62 [11.82] (-61.08, -14.16)	-68.28 [10.54] (-89.20, -47.36)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	30.66 [14.88] (1.13, 60.19)		
MMRM: P-value	0.042		
Corrected Hedges' g (95% CI)	0.409 (-0.015, 0.834)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.32		
MPN0113 - Night Sweats at Week 24			
n	65	82	
Mean (SD)	1.1 (1.84)	1.3 (1.86)	
Median	0.0	0.0	
Q1, Q3	0.0, 1.0	0.0, 2.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	76%	87%	
Number of Subjects in Risk	70	87	
Return Rate in Risk (%)	93%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5913: Analysis of MPN-SAF Mean Questionnaire Item #13 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Night Sweats at Week 24 from Baseline			
n	59	68	
Mean (SD)	-1.7 (2.81)	-1.7 (2.31)	
Median	-1.0	-1.0	
Q1, Q3	-3.0, 0.0	-3.0, 0.0	
Min, Max	-9.0, 5.0	-8.0, 4.0	
Difference in Change from Baseline at Week 24			
n [1]	73	76	
n [2]	59	68	
MMRM: Least Squares Mean [SE] (95% CI)	-1.43 [0.24] (-1.90, -0.95)	-1.54 [0.23] (-1.99, -1.10)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.12 [0.30] (-0.47, 0.70)		
MMRM: P-value	0.69		
Corrected Hedges' g (95% CI)	0.063 (-0.286, 0.411)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.82		
Percent Change in Night Sweats at Week 24 from Baseline			
n	39	51	
Mean (SD)	-59.9 (56.32)	-67.0 (47.15)	
Median	-77.8	-100.0	
Q1, Q3	-100.0, -50.0	-100.0, -50.0	
Min, Max	-100.0, 200.0	-100.0, 100.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5913: Analysis of MPN-SAF Mean Questionnaire Item #13 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	48	58	
n [2]	39	51	
MMRM: Least Squares Mean [SE] (95% CI)	-49.33 [9.41] (-68.01, -30.66)	-64.88 [8.50] (-81.75, -48.01)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	15.55 [11.42] (-7.11, 38.21)		
MMRM: P-value	0.18		
Corrected Hedges' g (95% CI)	0.257 (-0.161, 0.676)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.35		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.5914: Analysis of MPN-SAF Mean Questionnaire Item #14 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
MPN0114 - Itching at Baseline		
n	77	76
Mean (SD)	1.8 (2.67)	1.8 (2.55)
Median	0.0	1.0
Q1, Q3	0.0, 3.0	0.0, 3.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
MPN0114 - Itching at Week 4		
n	76	90
Mean (SD)	1.2 (2.12)	0.8 (1.56)
Median	0.0	0.0
Q1, Q3	0.0, 1.0	0.0, 1.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	88%	96%
Number of Subjects in Risk	82	94
Return Rate in Risk (%)	93%	96%
Change in Itching at Week 4 from Baseline		
n	71	75
Mean (SD)	-0.5 (1.83)	-0.9 (2.52)
Median	0.0	0.0
Q1, Q3	-1.0, 0.0	-1.0, 0.0
Min, Max	-9.0, 3.0	-9.0, 9.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5914: Analysis of MPN-SAF Mean Questionnaire Item #14 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	73	76	
n [2]	71	75	
MMRM: Least Squares Mean [SE] (95% CI)	-0.36 [0.21] (-0.77, 0.04)	-0.77 [0.20] (-1.15, -0.38)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.40 [0.26] (-0.11, 0.92)		
MMRM: P-value	0.12		
Corrected Hedges' g (95% CI)	0.234 (-0.092, 0.560)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.11		
Percent Change in Itching at Week 4 from Baseline			
n	33	40	
Mean (SD)	-38.6 (66.27)	-32.3 (163.95)	
Median	-50.0	-78.9	
Q1, Q3	-100.0, 0.0	-100.0, -25.0	
Min, Max	-100.0, 150.0	-100.0, 900.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	34	40	
n [2]	33	40	
MMRM: Least Squares Mean [SE] (95% CI)	-41.19 [22.50] (-86.10, 3.73)	-33.24 [20.63] (-74.42, 7.94)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-7.94 [30.03] (-67.89, 52.01)		
MMRM: P-value	0.79		
Corrected Hedges' g (95% CI)	-0.061 (-0.522, 0.401)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.24		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5914: Analysis of MPN-SAF Mean Questionnaire Item #14 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPN0114 - Itching at Week 8			
n	70	86	
Mean (SD)	1.3 (1.89)	0.8 (1.46)	
Median	0.0	0.0	
Q1, Q3	0.0, 2.0	0.0, 1.0	
Min, Max	0.0, 7.0	0.0, 6.0	
Return Rate (%)	81%	91%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	91%	
Change in Itching at Week 8 from Baseline			
n	65	73	
Mean (SD)	-0.5 (1.77)	-0.9 (2.11)	
Median	0.0	0.0	
Q1, Q3	-1.0, 0.0	-1.0, 0.0	
Min, Max	-6.0, 4.0	-10.0, 2.0	
Difference in Change from Baseline at Week 8			
n [1]	73	76	
n [2]	65	73	
MMRM: Least Squares Mean [SE] (95% CI)	-0.28 [0.18] (-0.64, 0.08)	-0.79 [0.17] (-1.12, -0.46)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.51 [0.22] (0.08, 0.94)		
MMRM: P-value	0.021		
Corrected Hedges' g (95% CI)	0.350 (0.013, 0.686)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.30		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5914: Analysis of MPN-SAF Mean Questionnaire Item #14 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Itching at Week 8 from Baseline			
n	31	38	
Mean (SD)	-36.6 (56.90)	-52.9 (62.81)	
Median	-50.0	-76.4	
Q1, Q3	-75.0, 0.0	-100.0, -14.3	
Min, Max	-100.0, 100.0	-100.0, 200.0	
Difference in Percent Change from Baseline at Week 8			
n [1]	34	40	
n [2]	31	38	
MMRM: Least Squares Mean [SE] (95% CI)	-37.92 [11.12] (-60.12, -15.71)	-54.53 [10.02] (-74.53, -34.52)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	16.61 [13.91] (-11.17, 44.39)		
MMRM: P-value	0.24		
Corrected Hedges' g (95% CI)	0.266 (-0.211, 0.742)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.17		
MPN0114 - Itching at Week 12			
n	71	89	
Mean (SD)	1.3 (1.93)	0.9 (1.53)	
Median	0.0	0.0	
Q1, Q3	0.0, 2.0	0.0, 1.0	
Min, Max	0.0, 7.0	0.0, 6.0	
Return Rate (%)	83%	95%	
Number of Subjects in Risk	76	94	
Return Rate in Risk (%)	93%	95%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5914: Analysis of MPN-SAF Mean Questionnaire Item #14 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Itching at Week 12 from Baseline			
n	65	74	
Mean (SD)	-0.4 (1.95)	-0.7 (2.29)	
Median	0.0	0.0	
Q1, Q3	-1.0, 0.0	-1.0, 0.0	
Min, Max	-6.0, 6.0	-8.0, 5.0	
Difference in Change from Baseline at Week 12			
n [1]	73	76	
n [2]	65	74	
MMRM: Least Squares Mean [SE] (95% CI)	-0.35 [0.21] (-0.76, 0.06)	-0.62 [0.19] (-1.00, -0.24)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.27 [0.26] (-0.24, 0.78)		
MMRM: P-value	0.29		
Corrected Hedges' g (95% CI)	0.163 (-0.170, 0.497)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.52		
Percent Change in Itching at Week 12 from Baseline			
n	29	38	
Mean (SD)	-47.5 (57.61)	-46.1 (102.62)	
Median	-50.0	-77.5	
Q1, Q3	-100.0, -25.0	-100.0, -20.0	
Min, Max	-100.0, 100.0	-100.0, 500.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5914: Analysis of MPN-SAF Mean Questionnaire Item #14 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	34	40	
n [2]	29	38	
MMRM: Least Squares Mean [SE] (95% CI)	-51.50 [15.30] (-82.05, -20.94)	-48.33 [13.78] (-75.83, -20.82)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-3.17 [19.85] (-42.80, 36.47)		
MMRM: P-value	0.87		
Corrected Hedges' g (95% CI)	-0.037 (-0.521, 0.446)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.51		
MPN0114 - Itching at Week 16			
n	67	83	
Mean (SD)	1.5 (2.21)	0.9 (1.50)	
Median	1.0	0.0	
Q1, Q3	0.0, 2.0	0.0, 1.0	
Min, Max	0.0, 10.0	0.0, 6.0	
Return Rate (%)	78%	88%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	89%	91%	
Change in Itching at Week 16 from Baseline			
n	61	71	
Mean (SD)	-0.3 (2.16)	-0.9 (2.28)	
Median	0.0	0.0	
Q1, Q3	-1.0, 0.0	-1.0, 0.0	
Min, Max	-7.0, 5.0	-9.0, 4.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5914: Analysis of MPN-SAF Mean Questionnaire Item #14 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	73	76	
n [2]	61	71	
MMRM: Least Squares Mean [SE] (95% CI)	-0.23 [0.21] (-0.65, 0.19)	-0.75 [0.20] (-1.15, -0.36)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.53 [0.27] (0.00, 1.05)		
MMRM: P-value	0.051		
Corrected Hedges' g (95% CI)	0.314 (-0.030, 0.658)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.081		
Percent Change in Itching at Week 16 from Baseline			
n	27	37	
Mean (SD)	-18.1 (116.86)	-39.3 (111.19)	
Median	-50.0	-77.8	
Q1, Q3	-66.7, 0.0	-100.0, -25.0	
Min, Max	-100.0, 500.0	-100.0, 400.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	34	40	
n [2]	27	37	
MMRM: Least Squares Mean [SE] (95% CI)	-22.84 [20.71] (-64.19, 18.51)	-42.15 [18.20] (-78.49, -5.81)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	19.31 [27.03] (-34.67, 73.28)		
MMRM: P-value	0.48		
Corrected Hedges' g (95% CI)	0.174 (-0.323, 0.671)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.033		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5914: Analysis of MPN-SAF Mean Questionnaire Item #14 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPN0114 - Itching at Week 20			
n	64	83	
Mean (SD)	1.6 (2.64)	0.7 (1.39)	
Median	0.0	0.0	
Q1, Q3	0.0, 2.0	0.0, 1.0	
Min, Max	0.0, 10.0	0.0, 7.0	
Return Rate (%)	74%	88%	
Number of Subjects in Risk	74	90	
Return Rate in Risk (%)	86%	92%	
Change in Itching at Week 20 from Baseline			
n	59	69	
Mean (SD)	-0.2 (2.87)	-1.0 (2.39)	
Median	0.0	0.0	
Q1, Q3	-1.0, 0.0	-2.0, 0.0	
Min, Max	-8.0, 10.0	-9.0, 6.0	
Difference in Change from Baseline at Week 20			
n [1]	73	76	
n [2]	59	69	
MMRM: Least Squares Mean [SE] (95% CI)	-0.07 [0.26] (-0.58, 0.44)	-0.82 [0.24] (-1.29, -0.34)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.75 [0.33] (0.09, 1.41)		
MMRM: P-value	0.026		
Corrected Hedges' g (95% CI)	0.374 (0.023, 0.724)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.083		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn14-db.pdf 29AUG2023: 9:40

Table 2.5914: Analysis of MPN-SAF Mean Questionnaire Item #14 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Itching at Week 20 from Baseline			
n	26	37	
Mean (SD)	-24.1 (102.48)	-47.1 (122.24)	
Median	-50.0	-100.0	
Q1, Q3	-100.0, 0.0	-100.0, -42.9	
Min, Max	-100.0, 300.0	-100.0, 600.0	
Difference in Percent Change from Baseline at Week 20			
n [1]	34	40	
n [2]	26	37	
MMRM: Least Squares Mean [SE] (95% CI)	-28.65 [19.58] (-67.73, 10.44)	-50.24 [17.51] (-85.20, -15.28)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	21.59 [25.68] (-29.68, 72.87)		
MMRM: P-value	0.40		
Corrected Hedges' g (95% CI)	0.205 (-0.297, 0.708)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.044		
MPN0114 - Itching at Week 24			
n	65	82	
Mean (SD)	1.1 (2.07)	0.6 (1.13)	
Median	0.0	0.0	
Q1, Q3	0.0, 1.0	0.0, 1.0	
Min, Max	0.0, 10.0	0.0, 5.0	
Return Rate (%)	76%	87%	
Number of Subjects in Risk	70	87	
Return Rate in Risk (%)	93%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5914: Analysis of MPN-SAF Mean Questionnaire Item #14 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Itching at Week 24 from Baseline			
n	59	68	
Mean (SD)	-0.5 (1.96)	-1.0 (2.17)	
Median	0.0	0.0	
Q1, Q3	-2.0, 0.0	-1.5, 0.0	
Min, Max	-6.0, 5.0	-9.0, 3.0	
Difference in Change from Baseline at Week 24			
n [1]	73	76	
n [2]	59	68	
MMRM: Least Squares Mean [SE] (95% CI)	-0.41 [0.20] (-0.81, 0.00)	-0.87 [0.19] (-1.25, -0.49)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.46 [0.26] (-0.05, 0.97)		
MMRM: P-value	0.074		
Corrected Hedges' g (95% CI)	0.290 (-0.061, 0.640)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.29		
Percent Change in Itching at Week 24 from Baseline			
n	25	34	
Mean (SD)	-44.2 (73.09)	-57.8 (76.56)	
Median	-66.7	-100.0	
Q1, Q3	-100.0, -28.6	-100.0, -33.3	
Min, Max	-100.0, 200.0	-100.0, 200.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn14-db.pdf 29AUG2023: 9:40

Table 2.5914: Analysis of MPN-SAF Mean Questionnaire Item #14 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	**34**	**40**	
n [2]	**25**	**34**	
MMRM: Least Squares Mean [SE] (95% CI)	**-41.23 [18.24] (-77.65, -4.81)**	**-45.09 [16.39] (-77.82, -12.36)**	
MMRM: Least Squares Mean Difference [SE] (95% CI)	**3.86 [23.90] (-43.86, 51.58)**		
MMRM: P-value	**0.87**		
Corrected Hedges' g (95% CI)	**0.041 (-0.476, 0.557)**		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	**0.11**		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5915: Analysis of MPN-SAF Mean Questionnaire Item #15 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
MPN0115 - Bone Pain at Baseline		
n	77	76
Mean (SD)	2.7 (3.07)	2.0 (2.55)
Median	2.0	1.0
Q1, Q3	0.0, 4.0	0.0, 4.0
Min, Max	0.0, 10.0	0.0, 9.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
MPN0115 - Bone Pain at Week 4		
n	76	90
Mean (SD)	2.3 (3.03)	1.5 (2.08)
Median	1.0	0.5
Q1, Q3	0.0, 3.5	0.0, 3.0
Min, Max	0.0, 10.0	0.0, 8.0
Return Rate (%)	88%	96%
Number of Subjects in Risk	82	94
Return Rate in Risk (%)	93%	96%
Change in Bone Pain at Week 4 from Baseline		
n	71	75
Mean (SD)	-0.5 (2.37)	-0.5 (2.30)
Median	0.0	0.0
Q1, Q3	-2.0, 0.0	-1.0, 0.0
Min, Max	-7.0, 8.0	-6.0, 6.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn15-db.pdf 29AUG2023: 9:40

Table 2.5915: Analysis of MPN-SAF Mean Questionnaire Item #15 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	73	76	
n [2]	71	75	
MMRM: Least Squares Mean [SE] (95% CI)	-0.23 [0.28] (-0.78, 0.31)	-0.69 [0.26] (-1.20, -0.18)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.46 [0.33] (-0.21, 1.12)		
MMRM: P-value	0.18		
Corrected Hedges' g (95% CI)	0.199 (-0.126, 0.525)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.88		
Percent Change in Bone Pain at Week 4 from Baseline			
n	46	41	
Mean (SD)	-30.7 (65.98)	-27.9 (77.22)	
Median	-31.7	-50.0	
Q1, Q3	-100.0, 0.0	-100.0, 0.0	
Min, Max	-100.0, 200.0	-100.0, 200.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	47	41	
n [2]	46	41	
MMRM: Least Squares Mean [SE] (95% CI)	-30.77 [11.55] (-53.76, -7.78)	-31.09 [11.51] (-54.00, -8.19)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.33 [15.33] (-30.19, 30.84)		
MMRM: P-value	0.98		
Corrected Hedges' g (95% CI)	0.004 (-0.417, 0.425)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.54		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn15-db.pdf 29AUG2023: 9:40

Table 2.5915: Analysis of MPN-SAF Mean Questionnaire Item #15 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPN0115 - Bone Pain at Week 8			
n	70	86	
Mean (SD)	2.4 (2.98)	1.6 (2.08)	
Median	1.0	1.0	
Q1, Q3	0.0, 4.0	0.0, 3.0	
Min, Max	0.0, 10.0	0.0, 9.0	
Return Rate (%)	81%	91%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	91%	
Change in Bone Pain at Week 8 from Baseline			
n	65	73	
Mean (SD)	-0.3 (2.25)	-0.4 (2.62)	
Median	0.0	0.0	
Q1, Q3	-1.0, 0.0	-1.0, 0.0	
Min, Max	-6.0, 7.0	-7.0, 9.0	
Difference in Change from Baseline at Week 8			
n [1]	73	76	
n [2]	65	73	
MMRM: Least Squares Mean [SE] (95% CI)	0.06 [0.29] (-0.51, 0.63)	-0.57 [0.27] (-1.10, -0.04)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.63 [0.35] (-0.06, 1.33)		
MMRM: P-value	0.075		
Corrected Hedges' g (95% CI)	0.274 (-0.062, 0.610)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.48		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5915: Analysis of MPN-SAF Mean Questionnaire Item #15 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Bone Pain at Week 8 from Baseline			
n	43	39	
Mean (SD)	-20.4 (82.16)	-17.4 (88.09)	
Median	-25.0	-33.3	
Q1, Q3	-75.0, 0.0	-85.7, 0.0	
Min, Max	-100.0, 300.0	-100.0, 300.0	
Difference in Percent Change from Baseline at Week 8			
n [1]	47	41	
n [2]	43	39	
MMRM: Least Squares Mean [SE] (95% CI)	-17.61 [13.52] (-44.51, 9.29)	-22.62 [13.66] (-49.80, 4.57)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	5.00 [18.40] (-31.62, 41.63)		
MMRM: P-value	0.79		
Corrected Hedges' g (95% CI)	0.057 (-0.377, 0.490)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.66		
MPN0115 - Bone Pain at Week 12			
n	71	89	
Mean (SD)	2.1 (2.72)	1.7 (2.10)	
Median	1.0	1.0	
Q1, Q3	0.0, 3.0	0.0, 3.0	
Min, Max	0.0, 10.0	0.0, 9.0	
Return Rate (%)	83%	95%	
Number of Subjects in Risk	76	94	
Return Rate in Risk (%)	93%	95%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5915: Analysis of MPN-SAF Mean Questionnaire Item #15 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Bone Pain at Week 12 from Baseline			
n	65	74	
Mean (SD)	-0.6 (2.27)	-0.5 (2.22)	
Median	0.0	0.0	
Q1, Q3	-2.0, 0.0	-2.0, 0.0	
Min, Max	-7.0, 7.0	-7.0, 7.0	
Difference in Change from Baseline at Week 12			
n [1]	73	76	
n [2]	65	74	
MMRM: Least Squares Mean [SE] (95% CI)	-0.34 [0.26] (-0.86, 0.18)	-0.67 [0.24] (-1.15, -0.20)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.33 [0.31] (-0.28, 0.95)		
MMRM: P-value	0.29		
Corrected Hedges' g (95% CI)	0.158 (-0.176, 0.491)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.49		
Percent Change in Bone Pain at Week 12 from Baseline			
n	44	41	
Mean (SD)	-34.9 (61.45)	-16.5 (103.78)	
Median	-41.7	-44.4	
Q1, Q3	-81.3, 0.0	-75.0, 0.0	
Min, Max	-100.0, 250.0	-100.0, 400.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5915: Analysis of MPN-SAF Mean Questionnaire Item #15 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	47	41	
n [2]	44	41	
MMRM: Least Squares Mean [SE] (95% CI)	-32.14 [13.63] (-59.27, -5.02)	-19.64 [13.59] (-46.68, 7.40)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-12.51 [18.42] (-49.17, 24.16)		
MMRM: P-value	0.50		
Corrected Hedges' g (95% CI)	-0.140 (-0.566, 0.286)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.72		
MPN0115 - Bone Pain at Week 16			
n	67	83	
Mean (SD)	2.0 (2.50)	1.6 (2.08)	
Median	1.0	1.0	
Q1, Q3	0.0, 4.0	0.0, 3.0	
Min, Max	0.0, 9.0	0.0, 8.0	
Return Rate (%)	78%	88%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	89%	91%	
Change in Bone Pain at Week 16 from Baseline			
n	61	71	
Mean (SD)	-0.9 (2.60)	-0.6 (2.54)	
Median	-1.0	0.0	
Q1, Q3	-2.0, 0.0	-2.0, 0.0	
Min, Max	-8.0, 7.0	-7.0, 7.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5915: Analysis of MPN-SAF Mean Questionnaire Item #15 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	73	76	
n [2]	61	71	
MMRM: Least Squares Mean [SE] (95% CI)	-0.54 [0.28] (-1.09, 0.00)	-0.78 [0.25] (-1.29, -0.28)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.24 [0.33] (-0.41, 0.90)		
MMRM: P-value	0.46		
Corrected Hedges' g (95% CI)	0.113 (-0.230, 0.455)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.16		
Percent Change in Bone Pain at Week 16 from Baseline			
n	42	37	
Mean (SD)	-47.0 (58.52)	-36.3 (76.75)	
Median	-50.0	-50.0	
Q1, Q3	-100.0, -12.5	-100.0, 0.0	
Min, Max	-100.0, 200.0	-100.0, 200.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	47	41	
n [2]	42	37	
MMRM: Least Squares Mean [SE] (95% CI)	-43.95 [11.29] (-66.42, -21.48)	-40.00 [11.21] (-62.30, -17.69)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-3.95 [14.91] (-33.62, 25.71)		
MMRM: P-value	0.79		
Corrected Hedges' g (95% CI)	-0.055 (-0.497, 0.387)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.69		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn15-db.pdf 29AUG2023: 9:40

Table 2.5915: Analysis of MPN-SAF Mean Questionnaire Item #15 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPN0115 - Bone Pain at Week 20			
n	64	83	
Mean (SD)	1.9 (2.70)	1.8 (2.16)	
Median	1.0	1.0	
Q1, Q3	0.0, 2.0	0.0, 3.0	
Min, Max	0.0, 10.0	0.0, 9.0	
Return Rate (%)	74%	88%	
Number of Subjects in Risk	74	90	
Return Rate in Risk (%)	86%	92%	
Change in Bone Pain at Week 20 from Baseline			
n	59	69	
Mean (SD)	-1.0 (3.12)	-0.5 (2.49)	
Median	-1.0	0.0	
Q1, Q3	-2.0, 0.0	-2.0, 0.0	
Min, Max	-10.0, 10.0	-6.0, 7.0	
Difference in Change from Baseline at Week 20			
n [1]	73	76	
n [2]	59	69	
MMRM: Least Squares Mean [SE] (95% CI)	-0.65 [0.30] (-1.25, -0.05)	-0.63 [0.28] (-1.18, -0.08)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.02 [0.37] (-0.76, 0.72)		
MMRM: P-value	0.95		
Corrected Hedges' g (95% CI)	-0.010 (-0.358, 0.337)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.15		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn15-db.pdf 29AUG2023: 9:40

Table 2.5915: Analysis of MPN-SAF Mean Questionnaire Item #15 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Bone Pain at Week 20 from Baseline		
n	40	38
Mean (SD)	-45.8 (65.30)	-22.3 (83.55)
Median	-64.6	-47.2
Q1, Q3	-100.0, -10.0	-83.3, 0.0
Min, Max	-100.0, 200.0	-100.0, 200.0
Difference in Percent Change from Baseline at Week 20		
n [1]	47	41
n [2]	40	38
MMRM: Least Squares Mean [SE] (95% CI)	-42.26 [12.28] (-66.69, -17.83)	-27.23 [12.08] (-51.28, -3.19)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-15.03 [16.30] (-47.46, 17.41)	
MMRM: P-value	0.36	
Corrected Hedges' g (95% CI)	-0.195 (-0.640, 0.250)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.25	
MPN0115 - Bone Pain at Week 24		
n	65	82
Mean (SD)	1.7 (2.56)	1.6 (2.23)
Median	1.0	1.0
Q1, Q3	0.0, 2.0	0.0, 2.0
Min, Max	0.0, 10.0	0.0, 9.0
Return Rate (%)	76%	87%
Number of Subjects in Risk	70	87
Return Rate in Risk (%)	93%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5915: Analysis of MPN-SAF Mean Questionnaire Item #15 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Bone Pain at Week 24 from Baseline			
n	59	68	
Mean (SD)	-1.0 (2.52)	-0.4 (2.50)	
Median	-1.0	0.0	
Q1, Q3	-2.0, 0.0	-2.0, 0.0	
Min, Max	-7.0, 6.0	-6.0, 7.0	
Difference in Change from Baseline at Week 24			
n [1]	73	76	
n [2]	59	68	
MMRM: Least Squares Mean [SE] (95% CI)	-0.61 [0.29] (-1.19, -0.03)	-0.62 [0.27] (-1.16, -0.09)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.01 [0.36] (-0.70, 0.73)		
MMRM: P-value	0.97		
Corrected Hedges' g (95% CI)	0.006 (-0.343, 0.355)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.13		
Percent Change in Bone Pain at Week 24 from Baseline			
n	40	35	
Mean (SD)	-42.0 (79.58)	-19.2 (138.82)	
Median	-61.3	-60.0	
Q1, Q3	-100.0, -10.0	-85.7, 0.0	
Min, Max	-100.0, 300.0	-100.0, 700.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn15-db.pdf 29AUG2023: 9:40

Table 2.5915: Analysis of MPN-SAF Mean Questionnaire Item #15 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	47	41	
n [2]	40	35	
MMRM: Least Squares Mean [SE] (95% CI)	-35.69 [17.43] (-70.38, -1.01)	-21.41 [17.87] (-56.98, 14.16)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-14.28 [24.35] (-62.73, 34.17)		
MMRM: P-value	0.56		
Corrected Hedges' g (95% CI)	-0.131 (-0.585, 0.323)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.55		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

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Table 2.5916: Analysis of MPN-SAF Mean Questionnaire Item #16 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
MPN0116 - Fever at Baseline		
n	77	76
Mean (SD)	0.4 (1.35)	0.5 (1.75)
Median	0.0	0.0
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
MPN0116 - Fever at Week 4		
n	76	90
Mean (SD)	0.5 (1.52)	0.4 (1.59)
Median	0.0	0.0
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	0.0, 8.0	0.0, 9.0
Return Rate (%)	88%	96%
Number of Subjects in Risk	82	94
Return Rate in Risk (%)	93%	96%
Change in Fever at Week 4 from Baseline		
n	71	75
Mean (SD)	0.0 (2.04)	-0.3 (2.13)
Median	0.0	0.0
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	-9.0, 8.0	-10.0, 8.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn16-db.pdf 29AUG2023: 9:40

Table 2.5916: Analysis of MPN-SAF Mean Questionnaire Item #16 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	73	76	
n [2]	71	75	
MMRM: Least Squares Mean [SE] (95% CI)	0.41 [0.16] (0.10, 0.72)	0.08 [0.15] (-0.21, 0.38)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.32 [0.20] (-0.07, 0.72)		
MMRM: P-value	0.11		
Corrected Hedges' g (95% CI)	0.246 (-0.080, 0.571)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.30		
Percent Change in Fever at Week 4 from Baseline			
n	12	10	
Mean (SD)	-37.5 (126.36)	-95.0 (15.81)	
Median	-100.0	-100.0	
Q1, Q3	-100.0, -25.0	-100.0, -100.0	
Min, Max	-100.0, 300.0	-100.0, -50.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	12	10	
n [2]	12	10	
MMRM: Least Squares Mean [SE] (95% CI)	-13.75 [16.92] (-50.04, 22.54)	-42.46 [18.97] (-83.14, -1.79)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	28.72 [24.76] (-24.38, 81.82)		
MMRM: P-value	0.27		
Corrected Hedges' g (95% CI)	0.466 (-0.384, 1.317)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.73		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn16-db.pdf 29AUG2023: 9:40

Table 2.5916: Analysis of MPN-SAF Mean Questionnaire Item #16 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPN0116 - Fever at Week 8			
n	70	86	
Mean (SD)	0.7 (1.79)	0.4 (1.44)	
Median	0.0	0.0	
Q1, Q3	0.0, 0.0	0.0, 0.0	
Min, Max	0.0, 8.0	0.0, 9.0	
Return Rate (%)	81%	91%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	91%	
Change in Fever at Week 8 from Baseline			
n	65	73	
Mean (SD)	0.3 (1.79)	-0.3 (2.11)	
Median	0.0	0.0	
Q1, Q3	0.0, 0.0	0.0, 0.0	
Min, Max	-3.0, 8.0	-10.0, 9.0	
Difference in Change from Baseline at Week 8			
n [1]	73	76	
n [2]	65	73	
MMRM: Least Squares Mean [SE] (95% CI)	0.61 [0.20] (0.21, 1.01)	0.10 [0.19] (-0.27, 0.47)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.51 [0.26] (-0.01, 1.03)		
MMRM: P-value	0.054		
Corrected Hedges' g (95% CI)	0.315 (-0.022, 0.651)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.65		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn16-db.pdf 29AUG2023: 9:40

Table 2.5916: Analysis of MPN-SAF Mean Questionnaire Item #16 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Fever at Week 8 from Baseline		
n	11	9
Mean (SD)	-49.2 (83.37)	-90.0 (20.00)
Median	-100.0	-100.0
Q1, Q3	-100.0, -33.3	-100.0, -100.0
Min, Max	-100.0, 150.0	-100.0, -50.0
Difference in Percent Change from Baseline at Week 8		
n [1]	12	10
n [2]	11	9
MMRM: Least Squares Mean [SE] (95% CI)	-28.29 [14.01] (-58.33, 1.75)	-37.37 [16.20] (-72.10, -2.63)
MMRM: Least Squares Mean Difference [SE] (95% CI)	9.07 [20.42] (-34.72, 52.87)	
MMRM: P-value	0.66	
Corrected Hedges' g (95% CI)	0.183 (-0.699, 1.066)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.28	
MPN0116 - Fever at Week 12		
n	71	89
Mean (SD)	0.5 (1.56)	0.1 (0.43)
Median	0.0	0.0
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	0.0, 8.0	0.0, 3.0
Return Rate (%)	83%	95%
Number of Subjects in Risk	76	94
Return Rate in Risk (%)	93%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5916: Analysis of MPN-SAF Mean Questionnaire Item #16 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Change in Fever at Week 12 from Baseline		
n	65	74
Mean (SD)	0.1 (1.95)	-0.5 (1.75)
Median	0.0	0.0
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	-9.0, 8.0	-10.0, 1.0
Difference in Change from Baseline at Week 12		
n [1]	73	76
n [2]	65	74
MMRM: Least Squares Mean [SE] (95% CI)	0.49 [0.15] (0.19, 0.79)	-0.11 [0.14] (-0.39, 0.18)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.60 [0.19] (0.21, 0.98)	
MMRM: P-value	0.002	
Corrected Hedges' g (95% CI)	0.481 (0.143, 0.818)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.13	
Percent Change in Fever at Week 12 from Baseline		
n	11	10
Mean (SD)	-24.2 (115.32)	-93.0 (16.36)
Median	-100.0	-100.0
Q1, Q3	-100.0, 100.0	-100.0, -100.0
Min, Max	-100.0, 200.0	-100.0, -50.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5916: Analysis of MPN-SAF Mean Questionnaire Item #16 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	12	10	
n [2]	11	10	
MMRM: Least Squares Mean [SE] (95% CI)	-5.20 [22.16] (-52.73, 42.33)		-40.46 [23.87] (-91.66, 10.73)
MMRM: Least Squares Mean Difference [SE] (95% CI)	35.27 [32.11] (-33.60, 104.13)		
MMRM: P-value	0.29		
Corrected Hedges' g (95% CI)	0.455 (-0.413, 1.322)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.53		
MPN0116 - Fever at Week 16			
n	67	83	
Mean (SD)	0.7 (1.93)	0.4 (1.51)	
Median	0.0	0.0	
Q1, Q3	0.0, 0.0	0.0, 0.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	78%	88%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	89%	91%	
Change in Fever at Week 16 from Baseline			
n	61	71	
Mean (SD)	0.1 (1.94)	-0.2 (2.26)	
Median	0.0	0.0	
Q1, Q3	0.0, 0.0	0.0, 0.0	
Min, Max	-5.0, 8.0	-10.0, 10.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn16-db.pdf 29AUG2023: 9:40

Table 2.5916: Analysis of MPN-SAF Mean Questionnaire Item #16 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	73	76	
n [2]	61	71	
MMRM: Least Squares Mean [SE] (95% CI)	0.47 [0.20] (0.07, 0.88)	0.18 [0.19] (-0.19, 0.56)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.29 [0.27] (-0.24, 0.82)		
MMRM: P-value	0.28		
Corrected Hedges' g (95% CI)	0.180 (-0.163, 0.523)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.84		
Percent Change in Fever at Week 16 from Baseline			
n	11	9	
Mean (SD)	-9.6 (162.66)	-78.9 (50.11)	
Median	-100.0	-100.0	
Q1, Q3	-100.0, 0.0	-100.0, -100.0	
Min, Max	-100.0, 400.0	-100.0, 50.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	12	10	
n [2]	11	9	
MMRM: Least Squares Mean [SE] (95% CI)	10.51 [26.41] (-46.12, 67.14)	-26.21 [29.30] (-89.06, 36.63)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	36.72 [38.90] (-46.71, 120.15)		
MMRM: P-value	0.36		
Corrected Hedges' g (95% CI)	0.401 (-0.489, 1.291)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.27		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn16-db.pdf 29AUG2023: 9:40

Table 2.5916: Analysis of MPN-SAF Mean Questionnaire Item #16 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPN0116 - Fever at Week 20			
n	64	83	
Mean (SD)	0.9 (2.35)	0.3 (1.30)	
Median	0.0	0.0	
Q1, Q3	0.0, 0.0	0.0, 0.0	
Min, Max	0.0, 10.0	0.0, 9.0	
Return Rate (%)	74%	88%	
Number of Subjects in Risk	74	90	
Return Rate in Risk (%)	86%	92%	
Change in Fever at Week 20 from Baseline			
n	59	69	
Mean (SD)	0.5 (2.82)	-0.3 (2.17)	
Median	0.0	0.0	
Q1, Q3	0.0, 0.0	0.0, 0.0	
Min, Max	-9.0, 10.0	-10.0, 9.0	
Difference in Change from Baseline at Week 20			
n [1]	73	76	
n [2]	59	69	
MMRM: Least Squares Mean [SE] (95% CI)	0.82 [0.24] (0.36, 1.29)	0.09 [0.22] (-0.35, 0.52)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.74 [0.31] (0.12, 1.35)		
MMRM: P-value	0.019		
Corrected Hedges' g (95% CI)	0.404 (0.053, 0.755)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.35		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn16-db.pdf 29AUG2023: 9:40

Table 2.5916: Analysis of MPN-SAF Mean Questionnaire Item #16 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Fever at Week 20 from Baseline		
n	11	9
Mean (SD)	-22.7 (153.89)	-86.7 (33.17)
Median	-100.0	-100.0
Q1, Q3	-100.0, 0.0	-100.0, -100.0
Min, Max	-100.0, 400.0	-100.0, 0.0
Difference in Percent Change from Baseline at Week 20		
n [1]	12	10
n [2]	11	9
MMRM: Least Squares Mean [SE] (95% CI)	-2.88 [21.87] (-49.79, 44.04)	-34.06 [24.32] (-86.23, 18.10)
MMRM: Least Squares Mean Difference [SE] (95% CI)	31.18 [32.07] (-37.60, 99.97)	
MMRM: P-value	0.35	
Corrected Hedges' g (95% CI)	0.411 (-0.479, 1.301)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.93	
MPN0116 - Fever at Week 24		
n	65	82
Mean (SD)	0.4 (1.40)	0.3 (0.82)
Median	0.0	0.0
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	0.0, 10.0	0.0, 4.0
Return Rate (%)	76%	87%
Number of Subjects in Risk	70	87
Return Rate in Risk (%)	93%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5916: Analysis of MPN-SAF Mean Questionnaire Item #16 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Change in Fever at Week 24 from Baseline		
n	59	68
Mean (SD)	-0.1 (1.85)	-0.3 (2.03)
Median	0.0	0.0
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	-9.0, 8.0	-10.0, 4.0
Difference in Change from Baseline at Week 24		
n [1]	73	76
n [2]	59	68
MMRM: Least Squares Mean [SE] (95% CI)	0.40 [0.15] (0.11, 0.69)	0.12 [0.14] (-0.15, 0.39)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.28 [0.18] (-0.08, 0.64)	
MMRM: P-value	0.13	
Corrected Hedges' g (95% CI)	0.244 (-0.106, 0.594)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.91	
Percent Change in Fever at Week 24 from Baseline		
n	11	9
Mean (SD)	-10.6 (163.01)	-81.5 (37.68)
Median	-100.0	-100.0
Q1, Q3	-100.0, 0.0	-100.0, -100.0
Min, Max	-100.0, 400.0	-100.0, 0.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn16-db.pdf 29AUG2023: 9:40

Table 2.5916: Analysis of MPN-SAF Mean Questionnaire Item #16 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	12	10	
n [2]	11	9	
MMRM: Least Squares Mean [SE] (95% CI)	9.46 [26.15] (-46.62, 65.54)	-28.82 [29.02] (-91.07, 33.43)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	38.28 [38.52] (-44.34, 120.89)		
MMRM: P-value	0.34		
Corrected Hedges' g (95% CI)	0.422 (-0.469, 1.313)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.48		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

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Table 2.5917: Analysis of MPN-SAF Mean Questionnaire Item #17 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
MPN0117 - Weight Loss in 6 Months at Baseline		
n	77	76
Mean (SD)	3.3 (3.29)	3.0 (3.22)
Median	2.0	2.0
Q1, Q3	0.0, 6.0	0.0, 6.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
MPN0117 - Weight Loss in 6 Months at Week 4		
n	76	90
Mean (SD)	1.9 (2.64)	1.9 (2.64)
Median	1.0	0.0
Q1, Q3	0.0, 3.0	0.0, 3.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	88%	96%
Number of Subjects in Risk	82	94
Return Rate in Risk (%)	93%	96%
Change in Weight Loss in 6 Months at Week 4 from Baseline		
n	71	75
Mean (SD)	-1.3 (3.32)	-1.0 (2.84)
Median	0.0	0.0
Q1, Q3	-4.0, 0.0	-3.0, 0.0
Min, Max	-9.0, 8.0	-8.0, 6.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn17-db.pdf 29AUG2023: 9:41

Table 2.5917: Analysis of MPN-SAF Mean Questionnaire Item #17 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	73	76	
n [2]	71	75	
MMRM: Least Squares Mean [SE] (95% CI)	-0.55 [0.31] (-1.16, 0.06)	-0.66 [0.29] (-1.24, -0.08)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.11 [0.40] (-0.67, 0.89)		
MMRM: P-value	0.78		
Corrected Hedges' g (95% CI)	0.043 (-0.281, 0.368)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.55		
Percent Change in Weight Loss in 6 Months at Week 4 from Baseline			
n	47	43	
Mean (SD)	-37.8 (70.79)	-40.0 (81.98)	
Median	-62.5	-66.7	
Q1, Q3	-100.0, 0.0	-100.0, 0.0	
Min, Max	-100.0, 200.0	-100.0, 300.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	48	44	
n [2]	47	43	
MMRM: Least Squares Mean [SE] (95% CI)	-22.46 [11.40] (-45.12, 0.21)	-25.74 [11.69] (-48.99, -2.49)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	3.28 [15.71] (-27.95, 34.52)		
MMRM: P-value	0.83		
Corrected Hedges' g (95% CI)	0.042 (-0.372, 0.456)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.57		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn17-db.pdf 29AUG2023: 9:41

Table 2.5917: Analysis of MPN-SAF Mean Questionnaire Item #17 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPN0117 - Weight Loss in 6 Months at Week 8			
n	70	86	
Mean (SD)	2.1 (2.75)	1.4 (2.33)	
Median	1.0	0.0	
Q1, Q3	0.0, 3.0	0.0, 2.0	
Min, Max	0.0, 10.0	0.0, 9.0	
Return Rate (%)	81%	91%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	91%	
Change in Weight Loss in 6 Months at Week 8 from Baseline			
n	65	73	
Mean (SD)	-1.0 (3.21)	-1.4 (2.89)	
Median	0.0	0.0	
Q1, Q3	-3.0, 0.0	-3.0, 0.0	
Min, Max	-8.0, 10.0	-9.0, 7.0	
Difference in Change from Baseline at Week 8			
n [1]	73	76	
n [2]	65	73	
MMRM: Least Squares Mean [SE] (95% CI)	-0.32 [0.32] (-0.96, 0.32)	-1.04 [0.30] (-1.65, -0.44)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.73 [0.42] (-0.09, 1.55)		
MMRM: P-value	0.082		
Corrected Hedges' g (95% CI)	0.278 (-0.058, 0.613)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.96		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5917: Analysis of MPN-SAF Mean Questionnaire Item #17 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Weight Loss in 6 Months at Week 8 from Baseline			
n	42	41	
Mean (SD)	-45.9 (53.54)	-43.1 (83.24)	
Median	-52.8	-60.0	
Q1, Q3	-100.0, 0.0	-100.0, -28.6	
Min, Max	-100.0, 100.0	-100.0, 350.0	
Difference in Percent Change from Baseline at Week 8			
n [1]	48	44	
n [2]	42	41	
MMRM: Least Squares Mean [SE] (95% CI)	-29.86 [11.74] (-53.22, -6.51)	-26.83 [11.84] (-50.38, -3.28)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-3.03 [16.08] (-35.00, 28.94)		
MMRM: P-value	0.85		
Corrected Hedges' g (95% CI)	-0.040 (-0.470, 0.391)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.60		
MPN0117 - Weight Loss in 6 Months at Week 12			
n	71	89	
Mean (SD)	1.6 (2.25)	1.2 (2.17)	
Median	1.0	0.0	
Q1, Q3	0.0, 3.0	0.0, 2.0	
Min, Max	0.0, 8.0	0.0, 10.0	
Return Rate (%)	83%	95%	
Number of Subjects in Risk	76	94	
Return Rate in Risk (%)	93%	95%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5917: Analysis of MPN-SAF Mean Questionnaire Item #17 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Weight Loss in 6 Months at Week 12 from Baseline			
n	65	74	
Mean (SD)	-1.3 (3.10)	-1.6 (2.90)	
Median	-1.0	-0.5	
Q1, Q3	-3.0, 0.0	-4.0, 0.0	
Min, Max	-9.0, 7.0	-8.0, 7.0	
Difference in Change from Baseline at Week 12			
n [1]	73	76	
n [2]	65	74	
MMRM: Least Squares Mean [SE] (95% CI)	-0.77 [0.28] (-1.32, -0.22)	-1.23 [0.26] (-1.74, -0.72)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.46 [0.34] (-0.22, 1.14)		
MMRM: P-value	0.19		
Corrected Hedges' g (95% CI)	0.204 (-0.130, 0.538)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.74		
Percent Change in Weight Loss in 6 Months at Week 12 from Baseline			
n	43	42	
Mean (SD)	-42.2 (79.15)	-64.0 (56.77)	
Median	-75.0	-90.0	
Q1, Q3	-100.0, -25.0	-100.0, -50.0	
Min, Max	-100.0, 200.0	-100.0, 200.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5917: Analysis of MPN-SAF Mean Questionnaire Item #17 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	48	44	
n [2]	43	42	
MMRM: Least Squares Mean [SE] (95% CI)	-27.85 [10.76] (-49.24, -6.46)	-48.86 [10.75] (-70.23, -27.49)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	21.01 [14.55] (-7.92, 49.95)		
MMRM: P-value	0.15		
Corrected Hedges' g (95% CI)	0.297 (-0.131, 0.725)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.092		
MPN0117 - Weight Loss in 6 Months at Week 16			
n	67	83	
Mean (SD)	1.5 (2.37)	0.9 (1.83)	
Median	0.0	0.0	
Q1, Q3	0.0, 2.0	0.0, 1.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	78%	88%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	89%	91%	
Change in Weight Loss in 6 Months at Week 16 from Baseline			
n	61	71	
Mean (SD)	-1.4 (3.23)	-2.1 (2.84)	
Median	-1.0	-1.0	
Q1, Q3	-3.0, 0.0	-4.0, 0.0	
Min, Max	-9.0, 8.0	-8.0, 4.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5917: Analysis of MPN-SAF Mean Questionnaire Item #17 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	73	76	
n [2]	61	71	
MMRM: Least Squares Mean [SE] (95% CI)	-0.95 [0.26] (-1.47, -0.43)	-1.66 [0.24] (-2.15, -1.18)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.72 [0.32] (0.08, 1.36)		
MMRM: P-value	0.029		
Corrected Hedges' g (95% CI)	0.345 (0.000, 0.690)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.61		
Percent Change in Weight Loss in 6 Months at Week 16 from Baseline			
n	40	42	
Mean (SD)	-52.3 (88.23)	-73.0 (40.16)	
Median	-87.5	-100.0	
Q1, Q3	-100.0, -37.5	-100.0, -57.1	
Min, Max	-100.0, 400.0	-100.0, 50.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	48	44	
n [2]	40	42	
MMRM: Least Squares Mean [SE] (95% CI)	-41.14 [10.10] (-61.23, -21.05)	-57.68 [10.05] (-77.66, -37.70)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	16.54 [13.54] (-10.39, 43.46)		
MMRM: P-value	0.23		
Corrected Hedges' g (95% CI)	0.254 (-0.181, 0.689)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.37		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5917: Analysis of MPN-SAF Mean Questionnaire Item #17 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPN0117 - Weight Loss in 6 Months at Week 20			
n	64	83	
Mean (SD)	1.4 (2.47)	0.9 (1.88)	
Median	0.0	0.0	
Q1, Q3	0.0, 2.0	0.0, 1.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	74%	88%	
Number of Subjects in Risk	74	90	
Return Rate in Risk (%)	86%	92%	
Change in Weight Loss in 6 Months at Week 20 from Baseline			
n	59	69	
Mean (SD)	-1.8 (3.38)	-2.1 (3.17)	
Median	-1.0	-1.0	
Q1, Q3	-4.0, 0.0	-5.0, 0.0	
Min, Max	-8.0, 9.0	-9.0, 6.0	
Difference in Change from Baseline at Week 20			
n [1]	73	76	
n [2]	59	69	
MMRM: Least Squares Mean [SE] (95% CI)	-1.08 [0.28] (-1.63, -0.52)	-1.72 [0.26] (-2.23, -1.20)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.64 [0.35] (-0.05, 1.33)		
MMRM: P-value	0.068		
Corrected Hedges' g (95% CI)	0.295 (-0.054, 0.645)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.71		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5917: Analysis of MPN-SAF Mean Questionnaire Item #17 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Weight Loss in 6 Months at Week 20 from Baseline			
n	41	40	
Mean (SD)	-62.0 (83.57)	-71.9 (56.36)	
Median	-100.0	-100.0	
Q1, Q3	-100.0, -50.0	-100.0, -64.6	
Min, Max	-100.0, 400.0	-100.0, 150.0	
Difference in Percent Change from Baseline at Week 20			
n [1]	48	44	
n [2]	41	40	
MMRM: Least Squares Mean [SE] (95% CI)	-47.15 [10.47] (-67.96, -26.33)	-56.88 [10.50] (-77.76, -36.01)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	9.74 [14.14] (-18.38, 37.86)		
MMRM: P-value	0.49		
Corrected Hedges' g (95% CI)	0.145 (-0.292, 0.581)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.33		
MPN0117 - Weight Loss in 6 Months at Week 24			
n	65	82	
Mean (SD)	1.1 (2.07)	0.7 (1.81)	
Median	0.0	0.0	
Q1, Q3	0.0, 1.0	0.0, 0.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	76%	87%	
Number of Subjects in Risk	70	87	
Return Rate in Risk (%)	93%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5917: Analysis of MPN-SAF Mean Questionnaire Item #17 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Weight Loss in 6 Months at Week 24 from Baseline			
n	59	68	
Mean (SD)	-2.1 (3.35)	-2.0 (2.69)	
Median	-1.0	-0.5	
Q1, Q3	-5.0, 0.0	-4.0, 0.0	
Min, Max	-10.0, 8.0	-8.0, 2.0	
Difference in Change from Baseline at Week 24			
n [1]	73	76	
n [2]	59	68	
MMRM: Least Squares Mean [SE] (95% CI)	-1.25 [0.26] (-1.77, -0.74)	-1.80 [0.24] (-2.28, -1.33)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.55 [0.32] (-0.08, 1.18)		
MMRM: P-value	0.085		
Corrected Hedges' g (95% CI)	0.275 (-0.076, 0.625)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.33		
Percent Change in Weight Loss in 6 Months at Week 24 from Baseline			
n	42	37	
Mean (SD)	-58.5 (86.67)	-80.4 (36.46)	
Median	-100.0	-100.0	
Q1, Q3	-100.0, -50.0	-100.0, -85.7	
Min, Max	-100.0, 400.0	-100.0, 25.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5917: Analysis of MPN-SAF Mean Questionnaire Item #17 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	48	44	
n [2]	42	37	
MMRM: Least Squares Mean [SE] (95% CI)		-44.14 [9.87] (-63.78, -24.51)	-67.27 [10.00] (-87.15, -47.39)
MMRM: Least Squares Mean Difference [SE] (95% CI)		23.13 [13.32] (-3.36, 49.61)	
MMRM: P-value		0.086	
Corrected Hedges' g (95% CI)		0.366 (-0.079, 0.812)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value		0.16	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5918: Analysis of MPN-SAF Mean Questionnaire Item #18 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
MPN0118 - Overall Quality of Life at Baseline		
n	77	76
Mean (SD)	4.0 (2.83)	4.0 (2.41)
Median	4.0	4.0
Q1, Q3	2.0, 6.0	2.0, 5.5
Min, Max	0.0, 10.0	0.0, 9.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
MPN0118 - Overall Quality of Life at Week 4		
n	76	90
Mean (SD)	3.7 (2.52)	3.6 (2.33)
Median	4.0	3.5
Q1, Q3	2.0, 6.0	2.0, 5.0
Min, Max	0.0, 10.0	0.0, 9.0
Return Rate (%)	88%	96%
Number of Subjects in Risk	82	94
Return Rate in Risk (%)	93%	96%
Change in Overall Quality of Life at Week 4 from Baseline		
n	71	75
Mean (SD)	-0.4 (2.97)	-0.6 (2.79)
Median	0.0	-1.0
Q1, Q3	-2.0, 1.0	-3.0, 0.0
Min, Max	-10.0, 8.0	-7.0, 8.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn18-db.pdf 29AUG2023: 9:41

Table 2.5918: Analysis of MPN-SAF Mean Questionnaire Item #18 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	73	76	
n [2]	71	75	
MMRM: Least Squares Mean [SE] (95% CI)	0.11 [0.30] (-0.48, 0.71)	-0.26 [0.29] (-0.83, 0.30)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.38 [0.37] (-0.37, 1.12)		
MMRM: P-value	0.32		
Corrected Hedges' g (95% CI)	0.149 (-0.176, 0.474)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.26		
Percent Change in Overall Quality of Life at Week 4 from Baseline			
n	62	67	
Mean (SD)	19.5 (117.82)	0.0 (143.53)	
Median	0.0	-33.3	
Q1, Q3	-42.9, 50.0	-60.0, 0.0	
Min, Max	-100.0, 500.0	-100.0, 800.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	63	68	
n [2]	62	67	
MMRM: Least Squares Mean [SE] (95% CI)	31.89 [16.19] (-0.16, 63.94)	2.18 [15.35] (-28.20, 32.55)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	29.72 [21.06] (-11.97, 71.41)		
MMRM: P-value	0.16		
Corrected Hedges' g (95% CI)	0.233 (-0.113, 0.580)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.11		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn18-db.pdf 29AUG2023: 9:41

Table 2.5918: Analysis of MPN-SAF Mean Questionnaire Item #18 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPN0118 - Overall Quality of Life at Week 8			
n	70	86	
Mean (SD)	3.7 (2.51)	3.0 (2.04)	
Median	4.0	3.0	
Q1, Q3	2.0, 5.0	1.0, 5.0	
Min, Max	0.0, 10.0	0.0, 8.0	
Return Rate (%)	81%	91%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	91%	
Change in Overall Quality of Life at Week 8 from Baseline			
n	65	73	
Mean (SD)	-0.2 (2.84)	-0.9 (2.63)	
Median	0.0	-1.0	
Q1, Q3	-2.0, 1.0	-2.0, 1.0	
Min, Max	-9.0, 5.0	-9.0, 4.0	
Difference in Change from Baseline at Week 8			
n [1]	73	76	
n [2]	65	73	
MMRM: Least Squares Mean [SE] (95% CI)	0.23 [0.29] (-0.34, 0.80)	-0.60 [0.27] (-1.14, -0.07)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.83 [0.35] (0.13, 1.53)		
MMRM: P-value	0.020		
Corrected Hedges' g (95% CI)	0.357 (0.020, 0.694)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.28		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5918: Analysis of MPN-SAF Mean Questionnaire Item #18 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Overall Quality of Life at Week 8 from Baseline			
n	56	65	
Mean (SD)	17.6 (111.65)	-9.5 (88.20)	
Median	-5.0	-25.0	
Q1, Q3	-47.2, 41.7	-57.1, 16.7	
Min, Max	-100.0, 500.0	-100.0, 400.0	
Difference in Percent Change from Baseline at Week 8			
n [1]	63	68	
n [2]	56	65	
MMRM: Least Squares Mean [SE] (95% CI)	28.09 [12.86] (2.63, 53.55)		-8.91 [11.92] (-32.50, 14.67)
MMRM: Least Squares Mean Difference [SE] (95% CI)	37.00 [15.94] (5.46, 68.55)		
MMRM: P-value	0.022		
Corrected Hedges' g (95% CI)	0.382 (0.022, 0.743)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.13		
MPN0118 - Overall Quality of Life at Week 12			
n	71	89	
Mean (SD)	3.8 (2.36)	3.4 (2.31)	
Median	4.0	3.0	
Q1, Q3	2.0, 5.0	2.0, 5.0	
Min, Max	0.0, 10.0	0.0, 9.0	
Return Rate (%)	83%	95%	
Number of Subjects in Risk	76	94	
Return Rate in Risk (%)	93%	95%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5918: Analysis of MPN-SAF Mean Questionnaire Item #18 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Overall Quality of Life at Week 12 from Baseline			
n	65	74	
Mean (SD)	0.1 (3.00)	-0.7 (2.78)	
Median	0.0	-1.0	
Q1, Q3	-2.0, 2.0	-2.0, 1.0	
Min, Max	-9.0, 5.0	-9.0, 6.0	
Difference in Change from Baseline at Week 12			
n [1]	73	76	
n [2]	65	74	
MMRM: Least Squares Mean [SE] (95% CI)	0.48 [0.30] (-0.12, 1.09)	-0.29 [0.28] (-0.86, 0.27)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.78 [0.38] (0.03, 1.52)		
MMRM: P-value	0.041		
Corrected Hedges' g (95% CI)	0.315 (-0.020, 0.650)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.044		
Percent Change in Overall Quality of Life at Week 12 from Baseline			
n	55	66	
Mean (SD)	29.9 (109.29)	3.5 (105.13)	
Median	0.0	-20.0	
Q1, Q3	-50.0, 50.0	-50.0, 0.0	
Min, Max	-100.0, 400.0	-100.0, 600.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5918: Analysis of MPN-SAF Mean Questionnaire Item #18 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	63	68	
n [2]	55	66	
MMRM: Least Squares Mean [SE] (95% CI)	39.22 [12.75] (13.98, 64.46)		7.45 [11.71] (-15.74, 30.63)
MMRM: Least Squares Mean Difference [SE] (95% CI)	31.77 [15.69] (0.71, 62.83)		
MMRM: P-value	0.045		
Corrected Hedges' g (95% CI)	0.333 (-0.028, 0.693)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.026		
MPN0118 - Overall Quality of Life at Week 16			
n	67	83	
Mean (SD)	3.7 (2.47)	3.6 (2.24)	
Median	4.0	3.0	
Q1, Q3	1.0, 5.0	2.0, 5.0	
Min, Max	0.0, 10.0	0.0, 8.0	
Return Rate (%)	78%	88%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	89%	91%	
Change in Overall Quality of Life at Week 16 from Baseline			
n	61	71	
Mean (SD)	-0.1 (3.10)	-0.6 (2.82)	
Median	0.0	0.0	
Q1, Q3	-2.0, 2.0	-2.0, 1.0	
Min, Max	-9.0, 5.0	-9.0, 7.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5918: Analysis of MPN-SAF Mean Questionnaire Item #18 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	73	76	
n [2]	61	71	
MMRM: Least Squares Mean [SE] (95% CI)	0.41 [0.31] (-0.20, 1.02)	-0.24 [0.29] (-0.81, 0.32)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.65 [0.38] (-0.11, 1.41)		
MMRM: P-value	0.091		
Corrected Hedges' g (95% CI)	0.268 (-0.076, 0.611)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.23		
Percent Change in Overall Quality of Life at Week 16 from Baseline			
n	53	64	
Mean (SD)	27.9 (116.38)	1.1 (87.22)	
Median	0.0	-14.6	
Q1, Q3	-40.0, 60.0	-50.0, 18.3	
Min, Max	-100.0, 500.0	-100.0, 300.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	63	68	
n [2]	53	64	
MMRM: Least Squares Mean [SE] (95% CI)	35.01 [12.42] (10.42, 59.60)	3.56 [11.37] (-18.95, 26.06)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	31.45 [15.18] (1.42, 61.49)		
MMRM: P-value	0.040		
Corrected Hedges' g (95% CI)	0.344 (-0.022, 0.711)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.13		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5918: Analysis of MPN-SAF Mean Questionnaire Item #18 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
MPN0118 - Overall Quality of Life at Week 20		
n	64	83
Mean (SD)	3.6 (2.56)	3.5 (2.38)
Median	3.0	3.0
Q1, Q3	1.5, 5.0	1.0, 5.0
Min, Max	0.0, 10.0	0.0, 9.0
Return Rate (%)	74%	88%
Number of Subjects in Risk	74	90
Return Rate in Risk (%)	86%	92%
Change in Overall Quality of Life at Week 20 from Baseline		
n	59	69
Mean (SD)	-0.4 (2.81)	-0.5 (2.84)
Median	0.0	-1.0
Q1, Q3	-2.0, 1.0	-2.0, 1.0
Min, Max	-9.0, 6.0	-9.0, 7.0
Difference in Change from Baseline at Week 20		
n [1]	73	76
n [2]	59	69
MMRM: Least Squares Mean [SE] (95% CI)	0.24 [0.31] (-0.38, 0.86)	-0.22 [0.29] (-0.79, 0.36)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.46 [0.39] (-0.31, 1.23)	
MMRM: P-value	0.24	
Corrected Hedges' g (95% CI)	0.188 (-0.160, 0.536)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.45	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5918: Analysis of MPN-SAF Mean Questionnaire Item #18 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Overall Quality of Life at Week 20 from Baseline			
n	53	61	
Mean (SD)	10.8 (92.83)	7.4 (106.70)	
Median	0.0	-20.0	
Q1, Q3	-40.0, 0.0	-50.0, 0.0	
Min, Max	-100.0, 400.0	-100.0, 400.0	
Difference in Percent Change from Baseline at Week 20			
n [1]	63	68	
n [2]	53	61	
MMRM: Least Squares Mean [SE] (95% CI)	30.13 [13.65] (3.11, 57.14)		7.44 [12.66] (-17.62, 32.49)
MMRM: Least Squares Mean Difference [SE] (95% CI)	22.69 [17.11] (-11.19, 56.56)		
MMRM: P-value	0.19		
Corrected Hedges' g (95% CI)	0.227 (-0.142, 0.597)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.25		
MPN0118 - Overall Quality of Life at Week 24			
n	65	82	
Mean (SD)	3.7 (2.62)	3.3 (2.22)	
Median	3.0	3.0	
Q1, Q3	1.0, 6.0	2.0, 5.0	
Min, Max	0.0, 10.0	0.0, 9.0	
Return Rate (%)	76%	87%	
Number of Subjects in Risk	70	87	
Return Rate in Risk (%)	93%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5918: Analysis of MPN-SAF Mean Questionnaire Item #18 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Overall Quality of Life at Week 24 from Baseline			
n	59	68	
Mean (SD)	-0.1 (3.09)	-0.7 (2.80)	
Median	0.0	0.0	
Q1, Q3	-2.0, 2.0	-2.0, 1.0	
Min, Max	-9.0, 8.0	-9.0, 7.0	
Difference in Change from Baseline at Week 24			
n [1]	73	76	
n [2]	59	68	
MMRM: Least Squares Mean [SE] (95% CI)	0.54 [0.32] (-0.09, 1.18)	-0.23 [0.30] (-0.83, 0.36)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.78 [0.40] (-0.02, 1.57)		
MMRM: P-value	0.056		
Corrected Hedges' g (95% CI)	0.311 (-0.040, 0.662)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.33		
Percent Change in Overall Quality of Life at Week 24 from Baseline			
n	51	60	
Mean (SD)	17.4 (99.03)	3.9 (102.97)	
Median	0.0	-20.0	
Q1, Q3	-40.0, 50.0	-50.0, 6.3	
Min, Max	-100.0, 400.0	-100.0, 400.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn18-db.pdf 29AUG2023: 9:41

Table 2.5918: Analysis of MPN-SAF Mean Questionnaire Item #18 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	63	68	
n [2]	51	60	
MMRM: Least Squares Mean [SE] (95% CI)	40.31 [14.13] (12.33, 68.28)		14.39 [13.09] (-11.52, 40.30)
MMRM: Least Squares Mean Difference [SE] (95% CI)	25.92 [17.81] (-9.33, 61.16)		
MMRM: P-value	0.15		
Corrected Hedges' g (95% CI)	0.254 (-0.120, 0.629)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.24		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

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Table 2.5919: Analysis of MPN-SAF Mean Questionnaire Item #19 Score and Change from Baseline

Double-Blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
BFI0101 - Fatigue Right Now at Baseline		
n	77	76
Mean (SD)	3.9 (2.83)	4.1 (2.59)
Median	3.0	4.0
Q1, Q3	2.0, 6.0	2.0, 6.0
Min, Max	0.0, 10.0	0.0, 9.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
BFI0101 - Fatigue Right Now at Week 4		
n	76	90
Mean (SD)	3.3 (2.48)	3.0 (2.58)
Median	3.0	3.0
Q1, Q3	1.0, 4.5	1.0, 4.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	88%	96%
Number of Subjects in Risk	82	94
Return Rate in Risk (%)	93%	96%
Change in Fatigue Right Now at Week 4 from Baseline		
n	71	75
Mean (SD)	-0.5 (2.40)	-1.1 (2.44)
Median	-1.0	-1.0
Q1, Q3	-3.0, 2.0	-2.0, 0.0
Min, Max	-6.0, 4.0	-7.0, 6.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.

MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).

MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.

[1] Number of subjects with analysable data for one or more time points.

[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5919: Analysis of MPN-SAF Mean Questionnaire Item #19 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	73	76	
n [2]	71	75	
MMRM: Least Squares Mean [SE] (95% CI)	-0.09 [0.29] (-0.65, 0.48)	-0.65 [0.27] (-1.20, -0.11)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.56 [0.35] (-0.13, 1.26)		
MMRM: P-value	0.11		
Corrected Hedges' g (95% CI)	0.235 (-0.091, 0.560)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.19		
Percent Change in Fatigue Right Now at Week 4 from Baseline			
n	60	70	
Mean (SD)	-1.7 (80.36)	-21.2 (91.93)	
Median	-24.3	-33.3	
Q1, Q3	-50.0, 41.7	-66.7, 0.0	
Min, Max	-100.0, 300.0	-100.0, 600.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	61	71	
n [2]	60	70	
MMRM: Least Squares Mean [SE] (95% CI)	8.53 [11.95] (-15.13, 32.18)	-14.26 [11.03] (-36.09, 7.56)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	22.79 [14.90] (-6.70, 52.28)		
MMRM: P-value	0.13		
Corrected Hedges' g (95% CI)	0.245 (-0.101, 0.591)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.11		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5919: Analysis of MPN-SAF Mean Questionnaire Item #19 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
BFI0101 - Fatigue Right Now at Week 8		
n	70	86
Mean (SD)	3.5 (2.57)	3.3 (2.57)
Median	3.0	3.0
Q1, Q3	1.0, 5.0	1.0, 5.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	81%	91%
Number of Subjects in Risk	79	94
Return Rate in Risk (%)	89%	91%
Change in Fatigue Right Now at Week 8 from Baseline		
n	65	73
Mean (SD)	-0.3 (2.56)	-0.7 (2.43)
Median	0.0	0.0
Q1, Q3	-2.0, 1.0	-2.0, 1.0
Min, Max	-5.0, 6.0	-8.0, 5.0
Difference in Change from Baseline at Week 8		
n [1]	73	76
n [2]	65	73
MMRM: Least Squares Mean [SE] (95% CI)	0.25 [0.30] (-0.35, 0.85)	-0.35 [0.29] (-0.92, 0.22)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.60 [0.38] (-0.15, 1.34)	
MMRM: P-value	0.12	
Corrected Hedges' g (95% CI)	0.241 (-0.095, 0.576)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.45	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5919: Analysis of MPN-SAF Mean Questionnaire Item #19 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Fatigue Right Now at Week 8 from Baseline			
n	55	68	
Mean (SD)	1.2 (74.99)	-8.0 (84.06)	
Median	-25.0	-17.1	
Q1, Q3	-50.0, 33.3	-63.3, 7.1	
Min, Max	-100.0, 200.0	-100.0, 400.0	
Difference in Percent Change from Baseline at Week 8			
n [1]	61	71	
n [2]	55	68	
MMRM: Least Squares Mean [SE] (95% CI)	12.34 [11.38] (-10.18, 34.86)	-2.80 [10.38] (-23.34, 17.74)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	15.14 [13.96] (-12.49, 42.76)		
MMRM: P-value	0.28		
Corrected Hedges' g (95% CI)	0.177 (-0.179, 0.533)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.41		
BFI0101 - Fatigue Right Now at Week 12			
n	71	89	
Mean (SD)	3.6 (2.46)	3.2 (2.58)	
Median	3.0	3.0	
Q1, Q3	2.0, 5.0	1.0, 5.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	83%	95%	
Number of Subjects in Risk	76	94	
Return Rate in Risk (%)	93%	95%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5919: Analysis of MPN-SAF Mean Questionnaire Item #19 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Change in Fatigue Right Now at Week 12 from Baseline		
n	65	74
Mean (SD)	0.0 (2.76)	-0.8 (2.29)
Median	0.0	-1.0
Q1, Q3	-2.0, 2.0	-2.0, 1.0
Min, Max	-6.0, 6.0	-6.0, 6.0
Difference in Change from Baseline at Week 12		
n [1]	73	76
n [2]	65	74
MMRM: Least Squares Mean [SE] (95% CI)	0.44 [0.29] (-0.14, 1.02)	-0.31 [0.28] (-0.86, 0.24)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.75 [0.36] (0.04, 1.46)	
MMRM: P-value	0.040	
Corrected Hedges' g (95% CI)	0.313 (-0.022, 0.648)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.022	
Percent Change in Fatigue Right Now at Week 12 from Baseline		
n	55	69
Mean (SD)	16.5 (94.69)	-16.5 (55.62)
Median	0.0	-25.0
Q1, Q3	-50.0, 50.0	-55.6, 0.0
Min, Max	-100.0, 400.0	-100.0, 150.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5919: Analysis of MPN-SAF Mean Questionnaire Item #19 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	61	71	
n [2]	55	69	
MMRM: Least Squares Mean [SE] (95% CI)	27.83 [11.09] (5.89, 49.77)		-3.86 [10.05] (-23.76, 16.04)
MMRM: Least Squares Mean Difference [SE] (95% CI)	31.70 [13.48] (5.02, 58.37)		
MMRM: P-value	0.020		
Corrected Hedges' g (95% CI)	0.380 (0.022, 0.737)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.057		
BFI0101 - Fatigue Right Now at Week 16			
n	67	83	
Mean (SD)	3.6 (2.62)	3.2 (2.52)	
Median	3.0	3.0	
Q1, Q3	2.0, 5.0	1.0, 5.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	78%	88%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	89%	91%	
Change in Fatigue Right Now at Week 16 from Baseline			
n	61	71	
Mean (SD)	-0.1 (2.72)	-0.8 (2.33)	
Median	0.0	-1.0	
Q1, Q3	-2.0, 2.0	-2.0, 0.0	
Min, Max	-6.0, 6.0	-9.0, 4.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5919: Analysis of MPN-SAF Mean Questionnaire Item #19 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	73	76	
n [2]	61	71	
MMRM: Least Squares Mean [SE] (95% CI)	0.47 [0.30] (-0.13, 1.07)	-0.34 [0.29] (-0.90, 0.23)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.81 [0.37] (0.07, 1.55)		
MMRM: P-value	0.033		
Corrected Hedges' g (95% CI)	0.336 (-0.008, 0.681)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.11		
Percent Change in Fatigue Right Now at Week 16 from Baseline			
n	53	66	
Mean (SD)	15.7 (92.76)	-18.5 (60.73)	
Median	0.0	-18.3	
Q1, Q3	-44.4, 66.7	-60.0, 0.0	
Min, Max	-100.0, 400.0	-100.0, 200.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	61	71	
n [2]	53	66	
MMRM: Least Squares Mean [SE] (95% CI)	25.35 [10.76] (4.05, 46.65)	-9.68 [9.77] (-29.01, 9.65)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	35.03 [13.00] (9.29, 60.76)		
MMRM: P-value	0.008		
Corrected Hedges' g (95% CI)	0.441 (0.075, 0.807)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.053		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5919: Analysis of MPN-SAF Mean Questionnaire Item #19 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
BFI0101 - Fatigue Right Now at Week 20			
n	64	83	
Mean (SD)	3.6 (2.75)	3.0 (2.30)	
Median	3.0	3.0	
Q1, Q3	2.0, 5.0	1.0, 4.0	
Min, Max	0.0, 10.0	0.0, 9.0	
Return Rate (%)	74%	88%	
Number of Subjects in Risk	74	90	
Return Rate in Risk (%)	86%	92%	
Change in Fatigue Right Now at Week 20 from Baseline			
n	59	69	
Mean (SD)	-0.2 (2.95)	-1.0 (2.35)	
Median	0.0	-1.0	
Q1, Q3	-2.0, 1.0	-2.0, 0.0	
Min, Max	-7.0, 8.0	-9.0, 4.0	
Difference in Change from Baseline at Week 20			
n [1]	73	76	
n [2]	59	69	
MMRM: Least Squares Mean [SE] (95% CI)	0.54 [0.31] (-0.07, 1.16)	-0.58 [0.29] (-1.15, 0.00)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.12 [0.39] (0.35, 1.88)		
MMRM: P-value	0.004		
Corrected Hedges' g (95% CI)	0.461 (0.109, 0.813)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.15		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5919: Analysis of MPN-SAF Mean Questionnaire Item #19 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Fatigue Right Now at Week 20 from Baseline		
n	51	64
Mean (SD)	8.5 (90.08)	-16.7 (61.36)
Median	0.0	-25.0
Q1, Q3	-50.0, 40.0	-52.8, 0.0
Min, Max	-100.0, 400.0	-100.0, 200.0
Difference in Percent Change from Baseline at Week 20		
n [1]	61	71
n [2]	51	64
MMRM: Least Squares Mean [SE] (95% CI)	25.95 [11.04] (4.10, 47.79)	-11.73 [9.98] (-31.48, 8.02)
MMRM: Least Squares Mean Difference [SE] (95% CI)	37.67 [13.39] (11.17, 64.18)	
MMRM: P-value	0.006	
Corrected Hedges' g (95% CI)	0.471 (0.098, 0.844)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.14	
BFI0101 - Fatigue Right Now at Week 24		
n	65	82
Mean (SD)	3.4 (2.40)	3.0 (2.40)
Median	3.0	3.0
Q1, Q3	2.0, 4.0	1.0, 4.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	76%	87%
Number of Subjects in Risk	70	87
Return Rate in Risk (%)	93%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5919: Analysis of MPN-SAF Mean Questionnaire Item #19 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Fatigue Right Now at Week 24 from Baseline			
n	59	68	
Mean (SD)	-0.2 (2.94)	-0.9 (2.12)	
Median	0.0	-1.0	
Q1, Q3	-2.0, 2.0	-2.0, 0.0	
Min, Max	-7.0, 8.0	-7.0, 4.0	
Difference in Change from Baseline at Week 24			
n [1]	73	76	
n [2]	59	68	
MMRM: Least Squares Mean [SE] (95% CI)	0.47 [0.30] (-0.13, 1.07)		-0.41 [0.29] (-0.97, 0.16)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.88 [0.37] (0.14, 1.62)		
MMRM: P-value	0.020		
Corrected Hedges' g (95% CI)	0.372 (0.021, 0.724)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.17		
Percent Change in Fatigue Right Now at Week 24 from Baseline			
n	50	63	
Mean (SD)	11.5 (97.44)	-17.3 (72.41)	
Median	-23.6	-33.3	
Q1, Q3	-50.0, 33.3	-57.1, 0.0	
Min, Max	-100.0, 300.0	-100.0, 300.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5919: Analysis of MPN-SAF Mean Questionnaire Item #19 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	**61**	**71**	
n [2]	**50**	**63**	
MMRM: Least Squares Mean [SE] (95% CI)	**29.11 [11.71] (5.94, 52.28)**		**-7.21 [10.60] (-28.18, 13.77)**
MMRM: Least Squares Mean Difference [SE] (95% CI)	**36.32 [14.39] (7.84, 64.80)**		
MMRM: P-value	**0.013**		
Corrected Hedges' g (95% CI)	**0.432 (0.056, 0.807)**		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	**0.11**		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

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Table 2.5920: Analysis of MPN-SAF Mean Questionnaire Item #20 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
BFI0102 - Usual Fatigue Level Past 24 Hours at Baseline		
n	77	76
Mean (SD)	4.3 (2.52)	4.3 (2.49)
Median	4.0	4.0
Q1, Q3	3.0, 6.0	2.0, 7.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
BFI0102 - Usual Fatigue Level Past 24 Hours at Week 4		
n	76	90
Mean (SD)	3.7 (2.46)	3.3 (2.51)
Median	3.0	3.0
Q1, Q3	2.0, 5.0	1.0, 5.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	88%	96%
Number of Subjects in Risk	82	94
Return Rate in Risk (%)	93%	96%
Change in Usual Fatigue Level Past 24 Hours at Week 4 from Baseline		
n	71	75
Mean (SD)	-0.5 (1.93)	-1.1 (2.20)
Median	0.0	-1.0
Q1, Q3	-2.0, 1.0	-2.0, 0.0
Min, Max	-7.0, 4.0	-6.0, 6.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5920: Analysis of MPN-SAF Mean Questionnaire Item #20 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	73	76	
n [2]	71	75	
MMRM: Least Squares Mean [SE] (95% CI)	-0.04 [0.26] (-0.55, 0.47)	-0.68 [0.25] (-1.17, -0.20)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.64 [0.31] (0.02, 1.26)		
MMRM: P-value	0.044		
Corrected Hedges' g (95% CI)	0.296 (-0.031, 0.622)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.028		
Percent Change in Usual Fatigue Level Past 24 Hours at Week 4 from Baseline			
n	66	72	
Mean (SD)	-6.2 (54.06)	-24.4 (51.35)	
Median	0.0	-28.6	
Q1, Q3	-40.0, 12.5	-50.0, 0.0	
Min, Max	-100.0, 200.0	-100.0, 200.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	67	73	
n [2]	66	72	
MMRM: Least Squares Mean [SE] (95% CI)	2.97 [7.26] (-11.39, 17.33)	-17.63 [6.84] (-31.15, -4.11)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	20.60 [8.98] (2.84, 38.36)		
MMRM: P-value	0.023		
Corrected Hedges' g (95% CI)	0.350 (0.014, 0.687)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.008		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5920: Analysis of MPN-SAF Mean Questionnaire Item #20 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
BFI0102 - Usual Fatigue Level Past 24 Hours at Week 8			
n	70	86	
Mean (SD)	3.9 (2.47)	3.2 (2.43)	
Median	3.0	3.0	
Q1, Q3	2.0, 6.0	1.0, 5.0	
Min, Max	0.0, 10.0	0.0, 9.0	
Return Rate (%)	81%	91%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	91%	
Change in Usual Fatigue Level Past 24 Hours at Week 8 from Baseline			
n	65	73	
Mean (SD)	-0.3 (2.27)	-1.0 (2.40)	
Median	0.0	-1.0	
Q1, Q3	-2.0, 1.0	-2.0, 0.0	
Min, Max	-6.0, 6.0	-7.0, 4.0	
Difference in Change from Baseline at Week 8			
n [1]	73	76	
n [2]	65	73	
MMRM: Least Squares Mean [SE] (95% CI)		0.27 [0.29] (-0.30, 0.84)	-0.69 [0.27] (-1.23, -0.15)
MMRM: Least Squares Mean Difference [SE] (95% CI)		0.96 [0.36] (0.24, 1.68)	
MMRM: P-value		0.009	
Corrected Hedges' g (95% CI)		0.408 (0.070, 0.746)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value		0.100	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5920: Analysis of MPN-SAF Mean Questionnaire Item #20 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Usual Fatigue Level Past 24 Hours at Week 8 from Baseline		
n	61	70
Mean (SD)	1.7 (81.82)	-19.0 (60.87)
Median	-12.5	-26.8
Q1, Q3	-40.0, 33.3	-66.7, 0.0
Min, Max	-100.0, 500.0	-100.0, 150.0
Difference in Percent Change from Baseline at Week 8		
n [1]	67	73
n [2]	61	70
MMRM: Least Squares Mean [SE] (95% CI)	9.58 [9.48] (-9.18, 28.34)	-13.60 [8.84] (-31.09, 3.89)
MMRM: Least Squares Mean Difference [SE] (95% CI)	23.18 [12.22] (-0.99, 47.35)	
MMRM: P-value	0.060	
Corrected Hedges' g (95% CI)	0.311 (-0.034, 0.657)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.069	
BFI0102 - Usual Fatigue Level Past 24 Hours at Week 12		
n	71	89
Mean (SD)	3.7 (2.33)	3.3 (2.40)
Median	3.0	3.0
Q1, Q3	2.0, 5.0	2.0, 5.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	83%	95%
Number of Subjects in Risk	76	94
Return Rate in Risk (%)	93%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn20-db.pdf 29AUG2023: 9:42

Table 2.5920: Analysis of MPN-SAF Mean Questionnaire Item #20 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Usual Fatigue Level Past 24 Hours at Week 12 from Baseline			
n	65	74	
Mean (SD)	-0.3 (2.34)	-1.0 (2.13)	
Median	0.0	-1.0	
Q1, Q3	-2.0, 1.0	-2.0, 0.0	
Min, Max	-6.0, 5.0	-7.0, 4.0	
Difference in Change from Baseline at Week 12			
n [1]	73	76	
n [2]	65	74	
MMRM: Least Squares Mean [SE] (95% CI)	0.18 [0.27] (-0.34, 0.71)	-0.51 [0.25] (-1.00, -0.01)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.69 [0.33] (0.04, 1.34)		
MMRM: P-value	0.036		
Corrected Hedges' g (95% CI)	0.318 (-0.017, 0.653)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.053		
Percent Change in Usual Fatigue Level Past 24 Hours at Week 12 from Baseline			
n	60	71	
Mean (SD)	-4.1 (59.60)	-20.4 (54.06)	
Median	0.0	-25.0	
Q1, Q3	-50.0, 29.2	-50.0, 0.0	
Min, Max	-100.0, 200.0	-100.0, 200.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5920: Analysis of MPN-SAF Mean Questionnaire Item #20 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	67	73	
n [2]	60	71	
MMRM: Least Squares Mean [SE] (95% CI)	5.99 [7.78] (-9.40, 21.38)		-12.13 [7.20] (-26.37, 2.10)
MMRM: Least Squares Mean Difference [SE] (95% CI)	18.12 [9.67] (-1.00, 37.25)		
MMRM: P-value	0.063		
Corrected Hedges' g (95% CI)	0.298 (-0.048, 0.644)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.11		
BFI0102 - Usual Fatigue Level Past 24 Hours at Week 16			
n	67	83	
Mean (SD)	3.7 (2.50)	3.2 (2.47)	
Median	3.0	3.0	
Q1, Q3	2.0, 5.0	1.0, 5.0	
Min, Max	0.0, 10.0	0.0, 9.0	
Return Rate (%)	78%	88%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	89%	91%	
Change in Usual Fatigue Level Past 24 Hours at Week 16 from Baseline			
n	61	71	
Mean (SD)	-0.5 (2.26)	-1.1 (2.26)	
Median	0.0	-1.0	
Q1, Q3	-2.0, 1.0	-2.0, 1.0	
Min, Max	-7.0, 5.0	-7.0, 3.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5920: Analysis of MPN-SAF Mean Questionnaire Item #20 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Change from Baseline at Week 16		
n [1]	73	76
n [2]	61	71
MMRM: Least Squares Mean [SE] (95% CI)	0.22 [0.28] (-0.34, 0.78)	-0.64 [0.27] (-1.17, -0.12)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.86 [0.35] (0.17, 1.55)	
MMRM: P-value	0.016	
Corrected Hedges' g (95% CI)	0.383 (0.038, 0.729)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.13	
Percent Change in Usual Fatigue Level Past 24 Hours at Week 16 from Baseline		
n	58	68
Mean (SD)	1.0 (84.94)	-22.3 (56.27)
Median	0.0	-35.4
Q1, Q3	-40.0, 33.3	-64.6, 13.4
Min, Max	-100.0, 500.0	-100.0, 100.0
Difference in Percent Change from Baseline at Week 16		
n [1]	67	73
n [2]	58	68
MMRM: Least Squares Mean [SE] (95% CI)	10.67 [9.32] (-7.76, 29.10)	-14.66 [8.64] (-31.75, 2.42)
MMRM: Least Squares Mean Difference [SE] (95% CI)	25.33 [11.94] (1.71, 48.95)	
MMRM: P-value	0.036	
Corrected Hedges' g (95% CI)	0.354 (0.001, 0.707)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.031	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5920: Analysis of MPN-SAF Mean Questionnaire Item #20 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
BFI0102 - Usual Fatigue Level Past 24 Hours at Week 20			
n	64	83	
Mean (SD)	3.7 (2.61)	3.2 (2.32)	
Median	3.0	3.0	
Q1, Q3	2.0, 5.0	1.0, 4.0	
Min, Max	0.0, 10.0	0.0, 9.0	
Return Rate (%)	74%	88%	
Number of Subjects in Risk	74	90	
Return Rate in Risk (%)	86%	92%	
Change in Usual Fatigue Level Past 24 Hours at Week 20 from Baseline			
n	59	69	
Mean (SD)	-0.5 (2.39)	-1.1 (2.13)	
Median	0.0	-1.0	
Q1, Q3	-2.0, 1.0	-2.0, 0.0	
Min, Max	-7.0, 5.0	-7.0, 3.0	
Difference in Change from Baseline at Week 20			
n [1]	73	76	
n [2]	59	69	
MMRM: Least Squares Mean [SE] (95% CI)	0.27 [0.28] (-0.29, 0.83)	-0.66 [0.27] (-1.18, -0.13)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.93 [0.35] (0.23, 1.62)		
MMRM: P-value	0.009		
Corrected Hedges' g (95% CI)	0.420 (0.069, 0.772)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.15		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5920: Analysis of MPN-SAF Mean Questionnaire Item #20 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Usual Fatigue Level Past 24 Hours at Week 20 from Baseline		
n	56	66
Mean (SD)	-1.1 (66.78)	-18.1 (53.01)
Median	-5.6	-25.0
Q1, Q3	-42.9, 37.5	-50.0, 0.0
Min, Max	-100.0, 200.0	-100.0, 150.0
Difference in Percent Change from Baseline at Week 20		
n [1]	67	73
n [2]	56	66
MMRM: Least Squares Mean [SE] (95% CI)	10.44 [8.15] (-5.68, 26.56)	-12.59 [7.53] (-27.49, 2.31)
MMRM: Least Squares Mean Difference [SE] (95% CI)	23.03 [10.22] (2.81, 43.24)	
MMRM: P-value	0.026	
Corrected Hedges' g (95% CI)	0.375 (0.015, 0.734)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.087	
BFI0102 - Usual Fatigue Level Past 24 Hours at Week 24		
n	65	82
Mean (SD)	3.3 (2.26)	3.1 (2.42)
Median	3.0	3.0
Q1, Q3	2.0, 4.0	1.0, 4.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	76%	87%
Number of Subjects in Risk	70	87
Return Rate in Risk (%)	93%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5920: Analysis of MPN-SAF Mean Questionnaire Item #20 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Usual Fatigue Level Past 24 Hours at Week 24 from Baseline			
n	59	68	
Mean (SD)	-0.7 (2.35)	-1.0 (2.12)	
Median	-1.0	-1.0	
Q1, Q3	-2.0, 1.0	-2.0, 0.0	
Min, Max	-7.0, 8.0	-6.0, 4.0	
Difference in Change from Baseline at Week 24			
n [1]	73	76	
n [2]	59	68	
MMRM: Least Squares Mean [SE] (95% CI)		0.03 [0.28] (-0.51, 0.58)	-0.51 [0.26] (-1.02, 0.00)
MMRM: Least Squares Mean Difference [SE] (95% CI)		0.55 [0.34] (-0.12, 1.21)	
MMRM: P-value	0.11		
Corrected Hedges' g (95% CI)	0.255 (-0.095, 0.605)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.50		
Percent Change in Usual Fatigue Level Past 24 Hours at Week 24 from Baseline			
n	55	65	
Mean (SD)	-10.8 (52.61)	-23.1 (51.32)	
Median	-20.0	-25.0	
Q1, Q3	-50.0, 33.3	-60.0, 0.0	
Min, Max	-100.0, 100.0	-100.0, 100.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5920: Analysis of MPN-SAF Mean Questionnaire Item #20 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	67	73	
n [2]	55	65	
MMRM: Least Squares Mean [SE] (95% CI)	0.71 [7.39] (-13.90, 15.33)		-15.32 [6.85] (-28.87, -1.76)
MMRM: Least Squares Mean Difference [SE] (95% CI)	16.03 [9.09] (-1.94, 34.00)		
MMRM: P-value	0.080		
Corrected Hedges' g (95% CI)	0.289 (-0.072, 0.650)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.10		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

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Table 2.5921: Analysis of MPN-SAF Mean Questionnaire Item #21 Score and Change from Baseline

Double-Blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
BFI0103 - Worst Fatigue Level Past 24 Hours at Baseline		
n	77	76
Mean (SD)	5.0 (2.85)	4.9 (2.60)
Median	5.0	5.0
Q1, Q3	3.0, 7.0	2.5, 7.0
Min, Max	0.0, 10.0	0.0, 9.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
BFI0103 - Worst Fatigue Level Past 24 Hours at Week 4		
n	76	90
Mean (SD)	4.2 (2.67)	3.7 (2.70)
Median	4.0	3.0
Q1, Q3	2.0, 6.0	2.0, 5.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	88%	96%
Number of Subjects in Risk	82	94
Return Rate in Risk (%)	93%	96%
Change in Worst Fatigue Level Past 24 Hours at Week 4 from Baseline		
n	71	75
Mean (SD)	-0.7 (2.17)	-1.3 (2.11)
Median	-1.0	-1.0
Q1, Q3	-2.0, 1.0	-3.0, 0.0
Min, Max	-7.0, 4.0	-6.0, 4.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.

MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).

MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.

[1] Number of subjects with analysable data for one or more time points.

[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5921: Analysis of MPN-SAF Mean Questionnaire Item #21 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	73	76	
n [2]	71	75	
MMRM: Least Squares Mean [SE] (95% CI)	-0.23 [0.27] (-0.76, 0.30)	-0.94 [0.25] (-1.44, -0.43)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.71 [0.33] (0.06, 1.36)		
MMRM: P-value	0.033		
Corrected Hedges' g (95% CI)	0.315 (-0.012, 0.641)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.055		
Percent Change in Worst Fatigue Level Past 24 Hours at Week 4 from Baseline			
n	65	72	
Mean (SD)	-10.4 (52.40)	-28.4 (43.40)	
Median	-14.3	-33.3	
Q1, Q3	-40.0, 14.3	-56.3, 0.0	
Min, Max	-100.0, 150.0	-100.0, 100.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	66	73	
n [2]	65	72	
MMRM: Least Squares Mean [SE] (95% CI)	-2.04 [6.72] (-15.33, 11.25)	-23.59 [6.25] (-35.95, -11.22)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	21.54 [8.30] (5.12, 37.97)		
MMRM: P-value	0.011		
Corrected Hedges' g (95% CI)	0.400 (0.061, 0.738)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.040		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5921: Analysis of MPN-SAF Mean Questionnaire Item #21 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
BFI0103 - Worst Fatigue Level Past 24 Hours at Week 8			
n	70	86	
Mean (SD)	4.2 (2.55)	3.8 (2.82)	
Median	4.0	3.0	
Q1, Q3	2.0, 6.0	1.0, 6.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	81%	91%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	91%	
Change in Worst Fatigue Level Past 24 Hours at Week 8 from Baseline			
n	65	73	
Mean (SD)	-0.8 (2.68)	-1.0 (2.54)	
Median	-1.0	-1.0	
Q1, Q3	-2.0, 1.0	-2.0, 1.0	
Min, Max	-7.0, 8.0	-9.0, 4.0	
Difference in Change from Baseline at Week 8			
n [1]	73	76	
n [2]	65	73	
MMRM: Least Squares Mean [SE] (95% CI)	-0.16 [0.31] (-0.78, 0.45)	-0.75 [0.30] (-1.33, -0.16)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.58 [0.40] (-0.20, 1.37)		
MMRM: P-value	0.14		
Corrected Hedges' g (95% CI)	0.230 (-0.105, 0.566)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.50		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5921: Analysis of MPN-SAF Mean Questionnaire Item #21 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Worst Fatigue Level Past 24 Hours at Week 8 from Baseline		
n	60	70
Mean (SD)	-12.6 (54.07)	-21.1 (52.91)
Median	-20.0	-20.0
Q1, Q3	-50.0, 11.8	-57.1, 0.0
Min, Max	-100.0, 200.0	-100.0, 133.3
Difference in Percent Change from Baseline at Week 8		
n [1]	66	73
n [2]	60	70
MMRM: Least Squares Mean [SE] (95% CI)	-5.70 [7.41] (-20.35, 8.95)	-17.40 [6.83] (-30.92, -3.88)
MMRM: Least Squares Mean Difference [SE] (95% CI)	11.70 [9.29] (-6.68, 30.07)	
MMRM: P-value	0.21	
Corrected Hedges' g (95% CI)	0.203 (-0.143, 0.549)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.34	
BFI0103 - Worst Fatigue Level Past 24 Hours at Week 12		
n	71	89
Mean (SD)	4.1 (2.40)	3.7 (2.48)
Median	4.0	3.0
Q1, Q3	3.0, 6.0	2.0, 5.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	83%	95%
Number of Subjects in Risk	76	94
Return Rate in Risk (%)	93%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5921: Analysis of MPN-SAF Mean Questionnaire Item #21 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Worst Fatigue Level Past 24 Hours at Week 12 from Baseline			
n	65	74	
Mean (SD)	-0.7 (2.47)	-1.2 (2.31)	
Median	-1.0	-1.0	
Q1, Q3	-2.0, 1.0	-3.0, 0.0	
Min, Max	-7.0, 5.0	-9.0, 4.0	
Difference in Change from Baseline at Week 12			
n [1]	73	76	
n [2]	65	74	
MMRM: Least Squares Mean [SE] (95% CI)	-0.22 [0.28] (-0.77, 0.33)	-0.82 [0.26] (-1.34, -0.31)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.61 [0.34] (-0.07, 1.28)		
MMRM: P-value	0.078		
Corrected Hedges' g (95% CI)	0.269 (-0.066, 0.604)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.27		
Percent Change in Worst Fatigue Level Past 24 Hours at Week 12 from Baseline			
n	59	71	
Mean (SD)	-5.4 (75.35)	-23.1 (46.55)	
Median	-16.7	-25.0	
Q1, Q3	-50.0, 0.0	-50.0, 0.0	
Min, Max	-100.0, 400.0	-100.0, 100.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5921: Analysis of MPN-SAF Mean Questionnaire Item #21 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	66	73	
n [2]	59	71	
MMRM: Least Squares Mean [SE] (95% CI)	2.02 [8.25] (-14.31, 18.35)		-17.46 [7.49] (-32.28, -2.63)
MMRM: Least Squares Mean Difference [SE] (95% CI)	19.47 [10.44] (-1.18, 40.13)		
MMRM: P-value	0.064		
Corrected Hedges' g (95% CI)	0.306 (-0.041, 0.653)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.31		
BFI0103 - Worst Fatigue Level Past 24 Hours at Week 16			
n	67	83	
Mean (SD)	4.1 (2.59)	3.9 (2.80)	
Median	4.0	4.0	
Q1, Q3	2.0, 6.0	1.0, 6.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	78%	88%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	89%	91%	
Change in Worst Fatigue Level Past 24 Hours at Week 16 from Baseline			
n	61	71	
Mean (SD)	-0.8 (2.37)	-1.1 (2.36)	
Median	-1.0	-1.0	
Q1, Q3	-2.0, 0.0	-2.0, 0.0	
Min, Max	-8.0, 6.0	-9.0, 4.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5921: Analysis of MPN-SAF Mean Questionnaire Item #21 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	73	76	
n [2]	61	71	
MMRM: Least Squares Mean [SE] (95% CI)	-0.20 [0.30] (-0.79, 0.39)		-0.70 [0.28] (-1.25, -0.15)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.50 [0.37] (-0.23, 1.23)		
MMRM: P-value	0.18		
Corrected Hedges' g (95% CI)	0.213 (-0.130, 0.556)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.61		
Percent Change in Worst Fatigue Level Past 24 Hours at Week 16 from Baseline			
n	57	68	
Mean (SD)	-13.3 (52.61)	-20.9 (46.71)	
Median	-20.0	-18.3	
Q1, Q3	-44.4, 0.0	-50.0, 0.0	
Min, Max	-100.0, 150.0	-100.0, 100.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	66	73	
n [2]	57	68	
MMRM: Least Squares Mean [SE] (95% CI)	-6.57 [6.89] (-20.19, 7.05)		-15.93 [6.31] (-28.41, -3.46)
MMRM: Least Squares Mean Difference [SE] (95% CI)	9.37 [8.48] (-7.41, 26.14)		
MMRM: P-value	0.27		
Corrected Hedges' g (95% CI)	0.179 (-0.174, 0.532)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.33		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5921: Analysis of MPN-SAF Mean Questionnaire Item #21 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
BFI0103 - Worst Fatigue Level Past 24 Hours at Week 20			
n	64	83	
Mean (SD)	4.1 (2.67)	3.5 (2.59)	
Median	4.0	3.0	
Q1, Q3	2.0, 6.0	1.0, 5.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	74%	88%	
Number of Subjects in Risk	74	90	
Return Rate in Risk (%)	86%	92%	
Change in Worst Fatigue Level Past 24 Hours at Week 20 from Baseline			
n	59	69	
Mean (SD)	-0.8 (2.53)	-1.3 (2.28)	
Median	-1.0	-1.0	
Q1, Q3	-3.0, 1.0	-3.0, 0.0	
Min, Max	-7.0, 4.0	-7.0, 4.0	
Difference in Change from Baseline at Week 20			
n [1]	73	76	
n [2]	59	69	
MMRM: Least Squares Mean [SE] (95% CI)	-0.10 [0.30] (-0.69, 0.50)	-0.97 [0.28] (-1.52, -0.42)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.88 [0.37] (0.14, 1.61)		
MMRM: P-value	0.020		
Corrected Hedges' g (95% CI)	0.377 (0.027, 0.728)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.24		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5921: Analysis of MPN-SAF Mean Questionnaire Item #21 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Worst Fatigue Level Past 24 Hours at Week 20 from Baseline			
n	55	66	
Mean (SD)	-7.4 (65.60)	-27.9 (44.65)	
Median	-20.0	-26.8	
Q1, Q3	-50.0, 16.7	-57.1, 0.0	
Min, Max	-100.0, 200.0	-100.0, 66.7	
Difference in Percent Change from Baseline at Week 20			
n [1]	66	73	
n [2]	55	66	
MMRM: Least Squares Mean [SE] (95% CI)	0.92 [7.60] (-14.10, 15.95)	-23.76 [6.94] (-37.49, -10.03)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	24.68 [9.52] (5.85, 43.52)		
MMRM: P-value	0.011		
Corrected Hedges' g (95% CI)	0.435 (0.073, 0.797)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.15		
BFI0103 - Worst Fatigue Level Past 24 Hours at Week 24			
n	65	82	
Mean (SD)	3.6 (2.42)	3.4 (2.48)	
Median	3.0	3.0	
Q1, Q3	2.0, 5.0	1.0, 5.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	76%	87%	
Number of Subjects in Risk	70	87	
Return Rate in Risk (%)	93%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5921: Analysis of MPN-SAF Mean Questionnaire Item #21 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Worst Fatigue Level Past 24 Hours at Week 24 from Baseline			
n	59	68	
Mean (SD)	-1.1 (2.90)	-1.2 (2.04)	
Median	-1.0	-1.0	
Q1, Q3	-3.0, 1.0	-2.0, 0.0	
Min, Max	-7.0, 9.0	-7.0, 4.0	
Difference in Change from Baseline at Week 24			
n [1]	73	76	
n [2]	59	68	
MMRM: Least Squares Mean [SE] (95% CI)	-0.42 [0.30] (-1.01, 0.16)		-0.90 [0.28] (-1.45, -0.35)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.48 [0.37] (-0.25, 1.21)		
MMRM: P-value	0.20		
Corrected Hedges' g (95% CI)	0.207 (-0.142, 0.557)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.99		
Percent Change in Worst Fatigue Level Past 24 Hours at Week 24 from Baseline			
n	54	65	
Mean (SD)	-18.0 (63.78)	-28.6 (41.23)	
Median	-33.3	-25.0	
Q1, Q3	-55.6, 0.0	-50.0, 0.0	
Min, Max	-100.0, 200.0	-100.0, 66.7	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5921: Analysis of MPN-SAF Mean Questionnaire Item #21 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	66	73	
n [2]	54	65	
MMRM: Least Squares Mean [SE] (95% CI)	-7.91 [7.35] (-22.46, 6.64)		-22.33 [6.73] (-35.64, -9.02)
MMRM: Least Squares Mean Difference [SE] (95% CI)	14.42 [9.17] (-3.72, 32.55)		
MMRM: P-value	0.12		
Corrected Hedges' g (95% CI)	0.265 (-0.098, 0.627)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.86		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5922: Analysis of MPN-SAF Mean Questionnaire Item #22 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
BFI0104 - Interfered Activity Past 24 Hours at Baseline		
n	77	76
Mean (SD)	4.1 (2.85)	4.2 (2.91)
Median	4.0	4.0
Q1, Q3	2.0, 6.0	2.0, 7.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
BFI0104 - Interfered Activity Past 24 Hours at Week 4		
n	76	90
Mean (SD)	3.2 (2.70)	3.0 (2.64)
Median	3.0	2.0
Q1, Q3	1.0, 5.0	1.0, 5.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	88%	96%
Number of Subjects in Risk	82	94
Return Rate in Risk (%)	93%	96%
Change in Interfered Activity Past 24 Hours at Week 4 from Baseline		
n	71	75
Mean (SD)	-0.8 (2.49)	-1.3 (2.40)
Median	0.0	-1.0
Q1, Q3	-2.0, 1.0	-3.0, 0.0
Min, Max	-8.0, 6.0	-7.0, 5.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5922: Analysis of MPN-SAF Mean Questionnaire Item #22 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	73	76	
n [2]	71	75	
MMRM: Least Squares Mean [SE] (95% CI)	-0.39 [0.28] (-0.95, 0.17)	-0.89 [0.27] (-1.42, -0.35)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.50 [0.35] (-0.20, 1.19)		
MMRM: P-value	0.16		
Corrected Hedges' g (95% CI)	0.210 (-0.115, 0.536)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.20		
Percent Change in Interfered Activity Past 24 Hours at Week 4 from Baseline			
n	63	66	
Mean (SD)	-4.5 (84.20)	-29.6 (59.81)	
Median	-14.3	-40.0	
Q1, Q3	-57.1, 25.0	-66.7, 0.0	
Min, Max	-100.0, 300.0	-100.0, 300.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	64	67	
n [2]	63	66	
MMRM: Least Squares Mean [SE] (95% CI)	2.49 [10.25] (-17.80, 22.77)	-21.88 [9.75] (-41.18, -2.57)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	24.36 [12.59] (-0.56, 49.28)		
MMRM: P-value	0.055		
Corrected Hedges' g (95% CI)	0.302 (-0.046, 0.649)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.048		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5922: Analysis of MPN-SAF Mean Questionnaire Item #22 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
BFI0104 - Interfered Activity Past 24 Hours at Week 8			
n	70	86	
Mean (SD)	3.6 (2.60)	3.0 (2.66)	
Median	3.0	2.5	
Q1, Q3	2.0, 5.0	1.0, 5.0	
Min, Max	0.0, 10.0	0.0, 9.0	
Return Rate (%)	81%	91%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	91%	
Change in Interfered Activity Past 24 Hours at Week 8 from Baseline			
n	65	73	
Mean (SD)	-0.3 (2.46)	-1.2 (2.71)	
Median	0.0	-1.0	
Q1, Q3	-1.0, 1.0	-2.0, 0.0	
Min, Max	-7.0, 8.0	-9.0, 5.0	
Difference in Change from Baseline at Week 8			
n [1]	73	76	
n [2]	65	73	
MMRM: Least Squares Mean [SE] (95% CI)	0.12 [0.30] (-0.47, 0.71)	-0.86 [0.28] (-1.42, -0.30)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.98 [0.38] (0.23, 1.73)		
MMRM: P-value	0.010		
Corrected Hedges' g (95% CI)	0.404 (0.066, 0.742)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.026		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5922: Analysis of MPN-SAF Mean Questionnaire Item #22 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Interfered Activity Past 24 Hours at Week 8 from Baseline			
n	57	64	
Mean (SD)	-1.8 (89.03)	-30.1 (76.78)	
Median	-14.3	-45.0	
Q1, Q3	-50.0, 0.0	-75.0, 0.0	
Min, Max	-100.0, 500.0	-100.0, 400.0	
Difference in Percent Change from Baseline at Week 8			
n [1]	64	67	
n [2]	57	64	
MMRM: Least Squares Mean [SE] (95% CI)	8.28 [12.30] (-16.07, 32.62)		-23.54 [11.55] (-46.41, -0.68)
MMRM: Least Squares Mean Difference [SE] (95% CI)	31.82 [15.59] (0.96, 62.68)		
MMRM: P-value	0.043		
Corrected Hedges' g (95% CI)	0.341 (-0.018, 0.701)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.003		
BFI0104 - Interfered Activity Past 24 Hours at Week 12			
n	71	89	
Mean (SD)	3.4 (2.54)	3.1 (2.63)	
Median	3.0	3.0	
Q1, Q3	2.0, 5.0	1.0, 5.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	83%	95%	
Number of Subjects in Risk	76	94	
Return Rate in Risk (%)	93%	95%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5922: Analysis of MPN-SAF Mean Questionnaire Item #22 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Interfered Activity Past 24 Hours at Week 12 from Baseline			
n	65	74	
Mean (SD)	-0.4 (2.41)	-1.1 (2.31)	
Median	0.0	-1.0	
Q1, Q3	-2.0, 1.0	-2.0, 0.0	
Min, Max	-6.0, 8.0	-9.0, 6.0	
Difference in Change from Baseline at Week 12			
n [1]	73	76	
n [2]	65	74	
MMRM: Least Squares Mean [SE] (95% CI)	0.01 [0.28] (-0.54, 0.56)		-0.68 [0.26] (-1.19, -0.17)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.69 [0.34] (0.01, 1.37)		
MMRM: P-value	0.047		
Corrected Hedges' g (95% CI)	0.306 (-0.030, 0.641)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.021		
Percent Change in Interfered Activity Past 24 Hours at Week 12 from Baseline			
n	57	66	
Mean (SD)	4.7 (82.25)	-23.9 (91.90)	
Median	-16.7	-33.3	
Q1, Q3	-40.0, 25.0	-66.7, 0.0	
Min, Max	-100.0, 300.0	-100.0, 600.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn22-db.pdf 29AUG2023: 9:42

Table 2.5922: Analysis of MPN-SAF Mean Questionnaire Item #22 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	64	67	
n [2]	57	66	
MMRM: Least Squares Mean [SE] (95% CI)	12.04 [12.18] (-12.06, 36.14)		-14.89 [11.41] (-37.47, 7.70)
MMRM: Least Squares Mean Difference [SE] (95% CI)	26.93 [15.39] (-3.54, 57.39)		
MMRM: P-value	0.083		
Corrected Hedges' g (95% CI)	0.290 (-0.066, 0.646)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.003		
BFI0104 - Interfered Activity Past 24 Hours at Week 16			
n	67	83	
Mean (SD)	3.6 (2.71)	2.8 (2.62)	
Median	3.0	3.0	
Q1, Q3	1.0, 6.0	0.0, 5.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	78%	88%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	89%	91%	
Change in Interfered Activity Past 24 Hours at Week 16 from Baseline			
n	61	71	
Mean (SD)	-0.2 (2.28)	-1.3 (2.39)	
Median	0.0	-1.0	
Q1, Q3	-2.0, 1.0	-2.0, 0.0	
Min, Max	-6.0, 8.0	-9.0, 5.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn22-db.pdf 29AUG2023: 9:42

Table 2.5922: Analysis of MPN-SAF Mean Questionnaire Item #22 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Change from Baseline at Week 16		
n [1]	73	76
n [2]	61	71
MMRM: Least Squares Mean [SE] (95% CI)	0.18 [0.28] (-0.38, 0.74)	-0.85 [0.27] (-1.38, -0.33)
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.04 [0.35] (0.34, 1.74)	
MMRM: P-value	0.004	
Corrected Hedges' g (95% CI)	0.461 (0.114, 0.808)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.010	
Percent Change in Interfered Activity Past 24 Hours at Week 16 from Baseline		
n	54	62
Mean (SD)	6.4 (93.41)	-35.1 (70.89)
Median	-5.0	-40.0
Q1, Q3	-42.9, 25.0	-77.8, 0.0
Min, Max	-100.0, 400.0	-100.0, 400.0
Difference in Percent Change from Baseline at Week 16		
n [1]	64	67
n [2]	54	62
MMRM: Least Squares Mean [SE] (95% CI)	17.58 [12.31] (-6.79, 41.96)	-26.40 [11.60] (-49.36, -3.44)
MMRM: Least Squares Mean Difference [SE] (95% CI)	43.98 [15.64] (13.03, 74.94)	
MMRM: P-value	0.006	
Corrected Hedges' g (95% CI)	0.480 (0.110, 0.850)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.001	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5922: Analysis of MPN-SAF Mean Questionnaire Item #22 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
BFI0104 - Interfered Activity Past 24 Hours at Week 20			
n	64	83	
Mean (SD)	3.5 (2.92)	2.9 (2.66)	
Median	3.0	2.0	
Q1, Q3	1.0, 5.0	0.0, 4.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	74%	88%	
Number of Subjects in Risk	74	90	
Return Rate in Risk (%)	86%	92%	
Change in Interfered Activity Past 24 Hours at Week 20 from Baseline			
n	59	69	
Mean (SD)	-0.4 (2.46)	-1.1 (2.32)	
Median	0.0	-1.0	
Q1, Q3	-2.0, 1.0	-3.0, 0.0	
Min, Max	-7.0, 5.0	-6.0, 6.0	
Difference in Change from Baseline at Week 20			
n [1]	73	76	
n [2]	59	69	
MMRM: Least Squares Mean [SE] (95% CI)	0.18 [0.30] (-0.42, 0.77)	-0.74 [0.28] (-1.29, -0.19)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.92 [0.38] (0.17, 1.66)		
MMRM: P-value	0.016		
Corrected Hedges' g (95% CI)	0.394 (0.043, 0.745)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.063		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5922: Analysis of MPN-SAF Mean Questionnaire Item #22 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Interfered Activity Past 24 Hours at Week 20 from Baseline			
n	52	61	
Mean (SD)	4.0 (88.76)	-26.9 (82.69)	
Median	-25.0	-40.0	
Q1, Q3	-45.0, 29.2	-66.7, 0.0	
Min, Max	-100.0, 400.0	-100.0, 500.0	
Difference in Percent Change from Baseline at Week 20			
n [1]	64	67	
n [2]	52	61	
MMRM: Least Squares Mean [SE] (95% CI)	21.32 [12.96] (-4.32, 46.97)		-18.62 [12.17] (-42.71, 5.48)
MMRM: Least Squares Mean Difference [SE] (95% CI)	39.94 [16.57] (7.15, 72.73)		
MMRM: P-value	0.017		
Corrected Hedges' g (95% CI)	0.421 (0.047, 0.795)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.016		
BFI0104 - Interfered Activity Past 24 Hours at Week 24			
n	65	82	
Mean (SD)	2.9 (2.26)	2.5 (2.41)	
Median	3.0	2.0	
Q1, Q3	1.0, 4.0	0.0, 4.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	76%	87%	
Number of Subjects in Risk	70	87	
Return Rate in Risk (%)	93%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5922: Analysis of MPN-SAF Mean Questionnaire Item #22 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Interfered Activity Past 24 Hours at Week 24 from Baseline			
n	59	68	
Mean (SD)	-0.8 (2.65)	-1.4 (2.27)	
Median	0.0	-1.0	
Q1, Q3	-3.0, 1.0	-3.0, 0.0	
Min, Max	-7.0, 5.0	-9.0, 5.0	
Difference in Change from Baseline at Week 24			
n [1]	73	76	
n [2]	59	68	
MMRM: Least Squares Mean [SE] (95% CI)	-0.35 [0.28] (-0.90, 0.20)		-1.01 [0.26] (-1.52, -0.49)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.66 [0.34] (-0.02, 1.34)		
MMRM: P-value	0.058		
Corrected Hedges' g (95% CI)	0.305 (-0.046, 0.656)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.13		
Percent Change in Interfered Activity Past 24 Hours at Week 24 from Baseline			
n	52	59	
Mean (SD)	-3.1 (108.72)	-41.1 (50.77)	
Median	-23.6	-44.4	
Q1, Q3	-66.7, 0.0	-75.0, 0.0	
Min, Max	-100.0, 500.0	-100.0, 200.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn22-db.pdf 29AUG2023: 9:42

Table 2.5922: Analysis of MPN-SAF Mean Questionnaire Item #22 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	64	67	
n [2]	52	59	
MMRM: Least Squares Mean [SE] (95% CI)	4.69 [11.53] (-18.13, 27.52)		-31.03 [10.88] (-52.56, -9.50)
MMRM: Least Squares Mean Difference [SE] (95% CI)	35.72 [14.47] (7.08, 64.37)		
MMRM: P-value	0.015		
Corrected Hedges' g (95% CI)	0.426 (0.049, 0.803)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.020		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

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Table 2.5923: Analysis of MPN-SAF Mean Questionnaire Item #23 Score and Change from Baseline

Double-Blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
BFI0105 - Interfered Mood Past 24 Hours at Baseline		
n	77	76
Mean (SD)	3.6 (2.93)	3.4 (2.81)
Median	3.0	3.0
Q1, Q3	1.0, 6.0	1.0, 5.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
BFI0105 - Interfered Mood Past 24 Hours at Week 4		
n	76	90
Mean (SD)	2.9 (2.74)	2.6 (2.34)
Median	2.0	2.0
Q1, Q3	0.5, 5.0	0.0, 4.0
Min, Max	0.0, 10.0	0.0, 8.0
Return Rate (%)	88%	96%
Number of Subjects in Risk	82	94
Return Rate in Risk (%)	93%	96%
Change in Interfered Mood Past 24 Hours at Week 4 from Baseline		
n	71	75
Mean (SD)	-0.7 (2.16)	-0.9 (2.18)
Median	0.0	-1.0
Q1, Q3	-2.0, 1.0	-2.0, 0.0
Min, Max	-7.0, 4.0	-9.0, 3.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.

MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).

MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.

[1] Number of subjects with analysable data for one or more time points.

[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5923: Analysis of MPN-SAF Mean Questionnaire Item #23 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	73	76	
n [2]	71	75	
MMRM: Least Squares Mean [SE] (95% CI)	-0.24 [0.25] (-0.73, 0.25)	-0.65 [0.24] (-1.12, -0.18)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.41 [0.31] (-0.20, 1.02)		
MMRM: P-value	0.19		
Corrected Hedges' g (95% CI)	0.197 (-0.129, 0.522)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.45		
Percent Change in Interfered Mood Past 24 Hours at Week 4 from Baseline			
n	57	63	
Mean (SD)	-19.8 (54.50)	-26.5 (57.40)	
Median	-28.6	-33.3	
Q1, Q3	-57.1, 0.0	-66.7, 0.0	
Min, Max	-100.0, 133.3	-100.0, 150.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	58	63	
n [2]	57	63	
MMRM: Least Squares Mean [SE] (95% CI)	-13.00 [8.38] (-29.61, 3.60)	-21.42 [7.82] (-36.92, -5.92)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	8.42 [10.51] (-12.41, 29.25)		
MMRM: P-value	0.43		
Corrected Hedges' g (95% CI)	0.133 (-0.225, 0.492)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.29		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn23-db.pdf 29AUG2023: 9:42

Table 2.5923: Analysis of MPN-SAF Mean Questionnaire Item #23 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
BFI0105 - Interfered Mood Past 24 Hours at Week 8			
n	70	86	
Mean (SD)	3.1 (2.63)	2.5 (2.48)	
Median	3.0	2.0	
Q1, Q3	1.0, 5.0	0.0, 4.0	
Min, Max	0.0, 9.0	0.0, 8.0	
Return Rate (%)	81%	91%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	91%	
Change in Interfered Mood Past 24 Hours at Week 8 from Baseline			
n	65	73	
Mean (SD)	-0.4 (2.39)	-1.1 (2.65)	
Median	0.0	-1.0	
Q1, Q3	-2.0, 1.0	-3.0, 0.0	
Min, Max	-7.0, 6.0	-9.0, 4.0	
Difference in Change from Baseline at Week 8			
n [1]	73	76	
n [2]	65	73	
MMRM: Least Squares Mean [SE] (95% CI)	0.07 [0.28] (-0.49, 0.62)		-0.82 [0.27] (-1.35, -0.30)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.89 [0.36] (0.19, 1.60)		
MMRM: P-value	0.014		
Corrected Hedges' g (95% CI)	0.391 (0.054, 0.728)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.16		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5923: Analysis of MPN-SAF Mean Questionnaire Item #23 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Interfered Mood Past 24 Hours at Week 8 from Baseline			
n	53	61	
Mean (SD)	-11.0 (82.09)	-31.0 (63.82)	
Median	-20.0	-42.9	
Q1, Q3	-50.0, 0.0	-80.0, 0.0	
Min, Max	-100.0, 300.0	-100.0, 200.0	
Difference in Percent Change from Baseline at Week 8			
n [1]	58	63	
n [2]	53	61	
MMRM: Least Squares Mean [SE] (95% CI)	-1.66 [10.55] (-22.57, 19.25)	-25.09 [9.81] (-44.53, -5.66)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	23.44 [13.67] (-3.64, 50.51)		
MMRM: P-value	0.089		
Corrected Hedges' g (95% CI)	0.303 (-0.067, 0.674)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.064		
BFI0105 - Interfered Mood Past 24 Hours at Week 12			
n	71	89	
Mean (SD)	2.9 (2.54)	2.4 (2.32)	
Median	2.0	2.0	
Q1, Q3	1.0, 5.0	0.0, 4.0	
Min, Max	0.0, 10.0	0.0, 8.0	
Return Rate (%)	83%	95%	
Number of Subjects in Risk	76	94	
Return Rate in Risk (%)	93%	95%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5923: Analysis of MPN-SAF Mean Questionnaire Item #23 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Interfered Mood Past 24 Hours at Week 12 from Baseline			
n	65	74	
Mean (SD)	-0.5 (2.24)	-0.9 (2.36)	
Median	0.0	-1.0	
Q1, Q3	-1.0, 1.0	-2.0, 0.0	
Min, Max	-7.0, 5.0	-9.0, 3.0	
Difference in Change from Baseline at Week 12			
n [1]	73	76	
n [2]	65	74	
MMRM: Least Squares Mean [SE] (95% CI)	0.01 [0.26] (-0.50, 0.52)		-0.68 [0.24] (-1.15, -0.20)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.68 [0.32] (0.05, 1.32)		
MMRM: P-value	0.036		
Corrected Hedges' g (95% CI)	0.326 (-0.010, 0.661)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.20		
Percent Change in Interfered Mood Past 24 Hours at Week 12 from Baseline			
n	52	61	
Mean (SD)	-17.0 (58.73)	-24.1 (63.92)	
Median	-25.0	-33.3	
Q1, Q3	-55.0, 0.0	-60.0, 0.0	
Min, Max	-100.0, 150.0	-100.0, 150.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5923: Analysis of MPN-SAF Mean Questionnaire Item #23 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	58	63	
n [2]	52	61	
MMRM: Least Squares Mean [SE] (95% CI)	-8.17 [9.31] (-26.62, 10.28)		-17.57 [8.56] (-34.53, -0.60)
MMRM: Least Squares Mean Difference [SE] (95% CI)	9.39 [11.80] (-13.98, 32.77)		
MMRM: P-value	0.43		
Corrected Hedges' g (95% CI)	0.139 (-0.231, 0.510)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.44		
BFI0105 - Interfered Mood Past 24 Hours at Week 16			
n	67	83	
Mean (SD)	3.1 (2.70)	2.4 (2.49)	
Median	3.0	2.0	
Q1, Q3	0.0, 5.0	0.0, 4.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	78%	88%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	89%	91%	
Change in Interfered Mood Past 24 Hours at Week 16 from Baseline			
n	61	71	
Mean (SD)	-0.4 (2.40)	-1.1 (2.45)	
Median	0.0	-1.0	
Q1, Q3	-2.0, 1.0	-2.0, 0.0	
Min, Max	-6.0, 6.0	-9.0, 4.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5923: Analysis of MPN-SAF Mean Questionnaire Item #23 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	73	76	
n [2]	61	71	
MMRM: Least Squares Mean [SE] (95% CI)	0.09 [0.28] (-0.47, 0.64)	-0.81 [0.26] (-1.33, -0.29)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.90 [0.36] (0.20, 1.60)		
MMRM: P-value	0.013		
Corrected Hedges' g (95% CI)	0.405 (0.060, 0.751)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.089		
Percent Change in Interfered Mood Past 24 Hours at Week 16 from Baseline			
n	50	58	
Mean (SD)	-16.0 (68.28)	-35.2 (62.49)	
Median	-25.0	-50.0	
Q1, Q3	-66.7, 20.0	-100.0, 0.0	
Min, Max	-100.0, 200.0	-100.0, 150.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	58	63	
n [2]	50	58	
MMRM: Least Squares Mean [SE] (95% CI)	-8.34 [9.79] (-27.73, 11.04)	-28.28 [9.04] (-46.20, -10.37)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	19.94 [12.52] (-4.85, 44.74)		
MMRM: P-value	0.11		
Corrected Hedges' g (95% CI)	0.287 (-0.093, 0.667)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.049		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5923: Analysis of MPN-SAF Mean Questionnaire Item #23 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
BFI0105 - Interfered Mood Past 24 Hours at Week 20			
n	64	83	
Mean (SD)	3.0 (2.77)	2.4 (2.60)	
Median	3.0	2.0	
Q1, Q3	1.0, 4.5	0.0, 3.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	74%	88%	
Number of Subjects in Risk	74	90	
Return Rate in Risk (%)	86%	92%	
Change in Interfered Mood Past 24 Hours at Week 20 from Baseline			
n	59	69	
Mean (SD)	-0.5 (2.22)	-1.2 (2.33)	
Median	0.0	-1.0	
Q1, Q3	-2.0, 1.0	-3.0, 0.0	
Min, Max	-7.0, 6.0	-8.0, 4.0	
Difference in Change from Baseline at Week 20			
n [1]	73	76	
n [2]	59	69	
MMRM: Least Squares Mean [SE] (95% CI)	0.07 [0.27] (-0.46, 0.61)	-0.87 [0.25] (-1.36, -0.37)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.94 [0.34] (0.27, 1.61)		
MMRM: P-value	0.006		
Corrected Hedges' g (95% CI)	0.449 (0.097, 0.800)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.10		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5923: Analysis of MPN-SAF Mean Questionnaire Item #23 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Interfered Mood Past 24 Hours at Week 20 from Baseline			
n	48	58	
Mean (SD)	-11.9 (65.01)	-37.9 (56.15)	
Median	-22.5	-50.0	
Q1, Q3	-63.3, 5.6	-100.0, 0.0	
Min, Max	-100.0, 200.0	-100.0, 100.0	
Difference in Percent Change from Baseline at Week 20			
n [1]	58	63	
n [2]	48	58	
MMRM: Least Squares Mean [SE] (95% CI)	-2.41 [9.23] (-20.69, 15.87)		-30.44 [8.44] (-47.15, -13.73)
MMRM: Least Squares Mean Difference [SE] (95% CI)	28.03 [11.63] (4.99, 51.07)		
MMRM: P-value	0.018		
Corrected Hedges' g (95% CI)	0.434 (0.047, 0.821)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.033		
BFI0105 - Interfered Mood Past 24 Hours at Week 24			
n	65	82	
Mean (SD)	2.5 (2.33)	2.1 (2.35)	
Median	2.0	2.0	
Q1, Q3	1.0, 4.0	0.0, 3.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	76%	87%	
Number of Subjects in Risk	70	87	
Return Rate in Risk (%)	93%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5923: Analysis of MPN-SAF Mean Questionnaire Item #23 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Interfered Mood Past 24 Hours at Week 24 from Baseline			
n	59	68	
Mean (SD)	-0.8 (2.24)	-1.2 (2.19)	
Median	0.0	-1.0	
Q1, Q3	-2.0, 1.0	-2.0, 0.0	
Min, Max	-7.0, 3.0	-9.0, 4.0	
Difference in Change from Baseline at Week 24			
n [1]	73	76	
n [2]	59	68	
MMRM: Least Squares Mean [SE] (95% CI)	-0.26 [0.25] (-0.76, 0.23)		-0.95 [0.23] (-1.41, -0.48)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.68 [0.31] (0.07, 1.29)		
MMRM: P-value	0.028		
Corrected Hedges' g (95% CI)	0.353 (0.002, 0.705)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.13		
Percent Change in Interfered Mood Past 24 Hours at Week 24 from Baseline			
n	47	55	
Mean (SD)	-22.5 (53.21)	-38.5 (52.39)	
Median	-25.0	-40.0	
Q1, Q3	-60.0, 0.0	-100.0, 0.0	
Min, Max	-100.0, 100.0	-100.0, 100.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5923: Analysis of MPN-SAF Mean Questionnaire Item #23 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	58	63	
n [2]	47	55	
MMRM: Least Squares Mean [SE] (95% CI)	-10.59 [8.28] (-27.00, 5.82)		-32.49 [7.66] (-47.65, -17.32)
MMRM: Least Squares Mean Difference [SE] (95% CI)	21.90 [10.29] (1.51, 42.29)		
MMRM: P-value	0.036		
Corrected Hedges' g (95% CI)	0.383 (-0.010, 0.776)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.043		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

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Table 2.5924: Analysis of MPN-SAF Mean Questionnaire Item #24 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
BFI0106 - Interfered Walking Past 24 Hours at Baseline		
n	77	76
Mean (SD)	3.9 (3.06)	4.2 (3.23)
Median	4.0	4.0
Q1, Q3	1.0, 7.0	1.0, 7.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
BFI0106 - Interfered Walking Past 24 Hours at Week 4		
n	76	90
Mean (SD)	3.3 (2.86)	3.0 (2.92)
Median	3.0	2.0
Q1, Q3	1.0, 5.5	0.0, 5.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	88%	96%
Number of Subjects in Risk	82	94
Return Rate in Risk (%)	93%	96%
Change in Interfered Walking Past 24 Hours at Week 4 from Baseline		
n	71	75
Mean (SD)	-0.6 (2.32)	-1.2 (2.39)
Median	-1.0	0.0
Q1, Q3	-2.0, 1.0	-3.0, 0.0
Min, Max	-8.0, 5.0	-9.0, 4.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5924: Analysis of MPN-SAF Mean Questionnaire Item #24 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	73	76	
n [2]	71	75	
MMRM: Least Squares Mean [SE] (95% CI)	-0.35 [0.28] (-0.90, 0.21)	-0.94 [0.27] (-1.47, -0.41)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.59 [0.35] (-0.09, 1.28)		
MMRM: P-value	0.090		
Corrected Hedges' g (95% CI)	0.253 (-0.073, 0.578)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.16		
Percent Change in Interfered Walking Past 24 Hours at Week 4 from Baseline			
n	60	59	
Mean (SD)	2.2 (112.17)	-23.4 (61.11)	
Median	-20.0	-28.6	
Q1, Q3	-53.6, 14.3	-66.7, 0.0	
Min, Max	-100.0, 500.0	-100.0, 200.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	61	60	
n [2]	60	59	
MMRM: Least Squares Mean [SE] (95% CI)	2.10 [12.70] (-23.05, 27.26)	-18.69 [12.50] (-43.45, 6.07)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	20.79 [16.38] (-11.65, 53.23)		
MMRM: P-value	0.21		
Corrected Hedges' g (95% CI)	0.213 (-0.148, 0.573)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.29		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5924: Analysis of MPN-SAF Mean Questionnaire Item #24 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
BFI0106 - Interfered Walking Past 24 Hours at Week 8			
n	70	86	
Mean (SD)	3.3 (2.83)	2.8 (2.67)	
Median	3.0	2.0	
Q1, Q3	1.0, 5.0	0.0, 4.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	81%	91%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	91%	
Change in Interfered Walking Past 24 Hours at Week 8 from Baseline			
n	65	73	
Mean (SD)	-0.4 (2.50)	-1.4 (2.64)	
Median	-1.0	-1.0	
Q1, Q3	-2.0, 1.0	-3.0, 0.0	
Min, Max	-6.0, 8.0	-9.0, 3.0	
Difference in Change from Baseline at Week 8			
n [1]	73	76	
n [2]	65	73	
MMRM: Least Squares Mean [SE] (95% CI)		-0.16 [0.30] (-0.75, 0.43)	-1.07 [0.28] (-1.63, -0.51)
MMRM: Least Squares Mean Difference [SE] (95% CI)		0.91 [0.38] (0.17, 1.65)	
MMRM: P-value		0.017	
Corrected Hedges' g (95% CI)		0.374 (0.037, 0.712)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value		0.13	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5924: Analysis of MPN-SAF Mean Questionnaire Item #24 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Interfered Walking Past 24 Hours at Week 8 from Baseline		
n	55	57
Mean (SD)	-6.2 (99.19)	-26.0 (74.23)
Median	-25.0	-37.5
Q1, Q3	-57.1, 0.0	-83.3, 0.0
Min, Max	-100.0, 500.0	-100.0, 300.0
Difference in Percent Change from Baseline at Week 8		
n [1]	61	60
n [2]	55	57
MMRM: Least Squares Mean [SE] (95% CI)	-8.31 [12.52] (-33.11, 16.49)	-20.36 [12.15] (-44.43, 3.72)
MMRM: Least Squares Mean Difference [SE] (95% CI)	12.05 [15.98] (-19.61, 43.71)	
MMRM: P-value	0.45	
Corrected Hedges' g (95% CI)	0.130 (-0.241, 0.501)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.25	
BFI0106 - Interfered Walking Past 24 Hours at Week 12		
n	71	89
Mean (SD)	3.1 (2.58)	2.8 (2.59)
Median	3.0	2.0
Q1, Q3	1.0, 5.0	0.0, 5.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	83%	95%
Number of Subjects in Risk	76	94
Return Rate in Risk (%)	93%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5924: Analysis of MPN-SAF Mean Questionnaire Item #24 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Interfered Walking Past 24 Hours at Week 12 from Baseline			
n	65	74	
Mean (SD)	-0.5 (2.38)	-1.3 (2.38)	
Median	0.0	-1.0	
Q1, Q3	-2.0, 1.0	-3.0, 0.0	
Min, Max	-5.0, 7.0	-9.0, 4.0	
Difference in Change from Baseline at Week 12			
n [1]	73	76	
n [2]	65	74	
MMRM: Least Squares Mean [SE] (95% CI)	-0.24 [0.27] (-0.77, 0.30)		-0.97 [0.26] (-1.47, -0.46)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.73 [0.33] (0.07, 1.39)		
MMRM: P-value	0.029		
Corrected Hedges' g (95% CI)	0.331 (-0.004, 0.667)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.11		
Percent Change in Interfered Walking Past 24 Hours at Week 12 from Baseline			
n	54	58	
Mean (SD)	9.8 (123.13)	-29.2 (58.86)	
Median	-25.0	-35.4	
Q1, Q3	-57.1, 25.0	-66.7, 0.0	
Min, Max	-100.0, 500.0	-100.0, 200.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5924: Analysis of MPN-SAF Mean Questionnaire Item #24 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	61	60	
n [2]	54	58	
MMRM: Least Squares Mean [SE] (95% CI)	9.86 [13.63] (-17.14, 36.86)		-21.87 [13.05] (-47.72, 3.99)
MMRM: Least Squares Mean Difference [SE] (95% CI)	31.72 [17.53] (-3.01, 66.46)		
MMRM: P-value	0.073		
Corrected Hedges' g (95% CI)	0.316 (-0.057, 0.689)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.11		
BFI0106 - Interfered Walking Past 24 Hours at Week 16			
n	67	83	
Mean (SD)	3.1 (2.74)	2.7 (2.67)	
Median	2.0	2.0	
Q1, Q3	1.0, 5.0	0.0, 4.0	
Min, Max	0.0, 10.0	0.0, 9.0	
Return Rate (%)	78%	88%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	89%	91%	
Change in Interfered Walking Past 24 Hours at Week 16 from Baseline			
n	61	71	
Mean (SD)	-0.6 (2.61)	-1.3 (2.55)	
Median	-1.0	-1.0	
Q1, Q3	-2.0, 1.0	-3.0, 0.0	
Min, Max	-7.0, 6.0	-9.0, 4.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn24-db.pdf 29AUG2023: 9:43

Table 2.5924: Analysis of MPN-SAF Mean Questionnaire Item #24 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	73	76	
n [2]	61	71	
MMRM: Least Squares Mean [SE] (95% CI)	-0.25 [0.30] (-0.85, 0.35)	-0.89 [0.28] (-1.45, -0.33)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.64 [0.38] (-0.11, 1.38)		
MMRM: P-value	0.092		
Corrected Hedges' g (95% CI)	0.268 (-0.076, 0.612)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.57		
Percent Change in Interfered Walking Past 24 Hours at Week 16 from Baseline			
n	52	56	
Mean (SD)	-1.3 (117.42)	-21.9 (76.56)	
Median	-33.3	-33.3	
Q1, Q3	-62.5, 16.3	-75.0, 0.0	
Min, Max	-100.0, 500.0	-100.0, 300.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	61	60	
n [2]	52	56	
MMRM: Least Squares Mean [SE] (95% CI)	-0.06 [13.75] (-27.30, 27.18)	-15.00 [13.30] (-41.35, 11.35)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	14.94 [17.81] (-20.34, 50.22)		
MMRM: P-value	0.40		
Corrected Hedges' g (95% CI)	0.149 (-0.229, 0.527)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.62		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn24-db.pdf 29AUG2023: 9:43

Table 2.5924: Analysis of MPN-SAF Mean Questionnaire Item #24 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
BFI0106 - Interfered Walking Past 24 Hours at Week 20			
n	64	83	
Mean (SD)	3.2 (2.97)	2.7 (2.82)	
Median	2.5	2.0	
Q1, Q3	1.0, 5.0	0.0, 5.0	
Min, Max	0.0, 10.0	0.0, 9.0	
Return Rate (%)	74%	88%	
Number of Subjects in Risk	74	90	
Return Rate in Risk (%)	86%	92%	
Change in Interfered Walking Past 24 Hours at Week 20 from Baseline			
n	59	69	
Mean (SD)	-0.5 (2.65)	-1.3 (2.72)	
Median	0.0	-1.0	
Q1, Q3	-2.0, 1.0	-3.0, 0.0	
Min, Max	-8.0, 7.0	-9.0, 5.0	
Difference in Change from Baseline at Week 20			
n [1]	73	76	
n [2]	59	69	
MMRM: Least Squares Mean [SE] (95% CI)		-0.12 [0.32] (-0.75, 0.52)	-0.94 [0.30] (-1.53, -0.34)
MMRM: Least Squares Mean Difference [SE] (95% CI)		0.82 [0.41] (0.02, 1.62)	
MMRM: P-value		0.045	
Corrected Hedges' g (95% CI)		0.329 (-0.021, 0.679)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value		0.21	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5924: Analysis of MPN-SAF Mean Questionnaire Item #24 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Interfered Walking Past 24 Hours at Week 20 from Baseline			
n	50	54	
Mean (SD)	10.0 (138.58)	-27.8 (72.89)	
Median	-22.5	-43.8	
Q1, Q3	-50.0, 33.3	-71.4, 0.0	
Min, Max	-100.0, 700.0	-100.0, 300.0	
Difference in Percent Change from Baseline at Week 20			
n [1]	61	60	
n [2]	50	54	
MMRM: Least Squares Mean [SE] (95% CI)	9.66 [15.23] (-20.52, 39.84)		-21.38 [14.71] (-50.52, 7.75)
MMRM: Least Squares Mean Difference [SE] (95% CI)	31.05 [19.99] (-8.55, 70.64)		
MMRM: P-value	0.12		
Corrected Hedges' g (95% CI)	0.286 (-0.101, 0.672)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.14		
BFI0106 - Interfered Walking Past 24 Hours at Week 24			
n	65	82	
Mean (SD)	2.9 (2.59)	2.5 (2.70)	
Median	2.0	2.0	
Q1, Q3	1.0, 4.0	0.0, 4.0	
Min, Max	0.0, 9.0	0.0, 10.0	
Return Rate (%)	76%	87%	
Number of Subjects in Risk	70	87	
Return Rate in Risk (%)	93%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5924: Analysis of MPN-SAF Mean Questionnaire Item #24 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Interfered Walking Past 24 Hours at Week 24 from Baseline			
n	59	68	
Mean (SD)	-0.8 (2.56)	-1.2 (2.79)	
Median	-1.0	-1.0	
Q1, Q3	-2.0, 1.0	-2.5, 0.0	
Min, Max	-8.0, 7.0	-9.0, 7.0	
Difference in Change from Baseline at Week 24			
n [1]	73	76	
n [2]	59	68	
MMRM: Least Squares Mean [SE] (95% CI)		-0.39 [0.31] (-1.01, 0.23)	-0.92 [0.30] (-1.51, -0.34)
MMRM: Least Squares Mean Difference [SE] (95% CI)		0.53 [0.40] (-0.25, 1.32)	
MMRM: P-value	0.18		
Corrected Hedges' g (95% CI)	0.218 (-0.132, 0.568)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.39		
Percent Change in Interfered Walking Past 24 Hours at Week 24 from Baseline			
n	49	52	
Mean (SD)	-10.2 (92.03)	-28.1 (82.12)	
Median	-33.3	-38.8	
Q1, Q3	-50.0, 0.0	-86.6, 0.0	
Min, Max	-100.0, 400.0	-100.0, 350.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn24-db.pdf 29AUG2023: 9:43

Table 2.5924: Analysis of MPN-SAF Mean Questionnaire Item #24 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	61	60	
n [2]	49	52	
MMRM: Least Squares Mean [SE] (95% CI)	2.59 [15.00] (-27.13, 32.32)		-19.06 [14.51] (-47.82, 9.69)
MMRM: Least Squares Mean Difference [SE] (95% CI)	21.66 [19.68] (-17.34, 60.65)		
MMRM: P-value	0.27		
Corrected Hedges' g (95% CI)	0.205 (-0.186, 0.596)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.25		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

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Table 2.5925: Analysis of MPN-SAF Mean Questionnaire Item #25 Score and Change from Baseline

Double-Blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
BFI0107 - Interfered Work Past 24 Hours at Baseline		
n	77	76
Mean (SD)	4.2 (3.07)	4.2 (3.15)
Median	4.0	4.0
Q1, Q3	2.0, 7.0	1.0, 7.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
BFI0107 - Interfered Work Past 24 Hours at Week 4		
n	76	90
Mean (SD)	3.2 (2.61)	3.0 (2.74)
Median	3.0	3.0
Q1, Q3	1.0, 5.0	1.0, 5.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	88%	96%
Number of Subjects in Risk	82	94
Return Rate in Risk (%)	93%	96%
Change in Interfered Work Past 24 Hours at Week 4 from Baseline		
n	71	75
Mean (SD)	-1.0 (2.45)	-1.1 (2.55)
Median	0.0	-1.0
Q1, Q3	-3.0, 0.0	-2.0, 0.0
Min, Max	-7.0, 4.0	-7.0, 7.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.

MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).

MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.

[1] Number of subjects with analysable data for one or more time points.

[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5925: Analysis of MPN-SAF Mean Questionnaire Item #25 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	73	76	
n [2]	71	75	
MMRM: Least Squares Mean [SE] (95% CI)	-0.66 [0.28] (-1.21, -0.11)	-0.84 [0.27] (-1.36, -0.31)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.17 [0.35] (-0.51, 0.86)		
MMRM: P-value	0.62		
Corrected Hedges' g (95% CI)	0.074 (-0.251, 0.398)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.26		
Percent Change in Interfered Work Past 24 Hours at Week 4 from Baseline			
n	59	62	
Mean (SD)	-13.9 (58.95)	-23.3 (66.96)	
Median	-10.0	-28.6	
Q1, Q3	-50.0, 0.0	-66.7, 0.0	
Min, Max	-100.0, 200.0	-100.0, 300.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	60	63	
n [2]	59	62	
MMRM: Least Squares Mean [SE] (95% CI)	-10.20 [9.03] (-28.08, 7.67)	-22.05 [8.56] (-39.00, -5.10)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	11.85 [11.26] (-10.46, 34.16)		
MMRM: P-value	0.29		
Corrected Hedges' g (95% CI)	0.172 (-0.185, 0.529)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.064		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5925: Analysis of MPN-SAF Mean Questionnaire Item #25 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
BFI0107 - Interfered Work Past 24 Hours at Week 8			
n	70	86	
Mean (SD)	3.7 (2.88)	2.9 (2.72)	
Median	3.0	2.5	
Q1, Q3	2.0, 6.0	0.0, 4.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	81%	91%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	91%	
Change in Interfered Work Past 24 Hours at Week 8 from Baseline			
n	65	73	
Mean (SD)	-0.4 (2.75)	-1.2 (2.59)	
Median	0.0	-1.0	
Q1, Q3	-2.0, 1.0	-3.0, 0.0	
Min, Max	-6.0, 8.0	-9.0, 5.0	
Difference in Change from Baseline at Week 8			
n [1]	73	76	
n [2]	65	73	
MMRM: Least Squares Mean [SE] (95% CI)	0.10 [0.31] (-0.51, 0.72)	-0.93 [0.29] (-1.50, -0.35)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.03 [0.39] (0.26, 1.80)		
MMRM: P-value	0.009		
Corrected Hedges' g (95% CI)	0.413 (0.075, 0.750)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.035		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn25-db.pdf 29AUG2023: 9:43

Table 2.5925: Analysis of MPN-SAF Mean Questionnaire Item #25 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Interfered Work Past 24 Hours at Week 8 from Baseline		
n	54	60
Mean (SD)	-9.7 (63.32)	-26.7 (81.32)
Median	-12.5	-41.4
Q1, Q3	-55.6, 12.5	-79.2, 0.0
Min, Max	-100.0, 200.0	-100.0, 300.0
Difference in Percent Change from Baseline at Week 8		
n [1]	60	63
n [2]	54	60
MMRM: Least Squares Mean [SE] (95% CI)	-7.09 [10.68] (-28.24, 14.05)	-22.50 [9.99] (-42.29, -2.70)
MMRM: Least Squares Mean Difference [SE] (95% CI)	15.40 [13.64] (-11.62, 42.42)	
MMRM: P-value	0.26	
Corrected Hedges' g (95% CI)	0.196 (-0.172, 0.565)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.011	
BFI0107 - Interfered Work Past 24 Hours at Week 12		
n	71	89
Mean (SD)	3.5 (2.50)	3.1 (2.65)
Median	3.0	3.0
Q1, Q3	2.0, 5.0	1.0, 5.0
Min, Max	0.0, 10.0	0.0, 9.0
Return Rate (%)	83%	95%
Number of Subjects in Risk	76	94
Return Rate in Risk (%)	93%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5925: Analysis of MPN-SAF Mean Questionnaire Item #25 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Change in Interfered Work Past 24 Hours at Week 12 from Baseline		
n	65	74
Mean (SD)	-0.4 (2.78)	-1.1 (2.22)
Median	0.0	-1.0
Q1, Q3	-3.0, 1.0	-2.0, 0.0
Min, Max	-6.0, 9.0	-7.0, 5.0
Difference in Change from Baseline at Week 12		
n [1]	73	76
n [2]	65	74
MMRM: Least Squares Mean [SE] (95% CI)	-0.01 [0.28] (-0.57, 0.55)	-0.73 [0.27] (-1.25, -0.20)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.72 [0.35] (0.03, 1.41)	
MMRM: P-value	0.041	
Corrected Hedges' g (95% CI)	0.313 (-0.022, 0.648)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.049	
Percent Change in Interfered Work Past 24 Hours at Week 12 from Baseline		
n	53	61
Mean (SD)	-6.5 (56.70)	-19.7 (70.70)
Median	-25.0	-33.3
Q1, Q3	-50.0, 40.0	-62.5, 0.0
Min, Max	-100.0, 100.0	-100.0, 250.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn25-db.pdf 29AUG2023: 9:43

Table 2.5925: Analysis of MPN-SAF Mean Questionnaire Item #25 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	60	63	
n [2]	53	61	
MMRM: Least Squares Mean [SE] (95% CI)	-0.95 [9.50] (-19.77, 17.87)		-14.35 [8.85] (-31.87, 3.18)
MMRM: Least Squares Mean Difference [SE] (95% CI)	13.40 [11.86] (-10.09, 36.89)		
MMRM: P-value	0.26		
Corrected Hedges' g (95% CI)	0.193 (-0.176, 0.561)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.069		
BFI0107 - Interfered Work Past 24 Hours at Week 16			
n	67	83	
Mean (SD)	3.5 (2.91)	3.1 (2.78)	
Median	3.0	3.0	
Q1, Q3	1.0, 6.0	0.0, 5.0	
Min, Max	0.0, 10.0	0.0, 9.0	
Return Rate (%)	78%	88%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	89%	91%	
Change in Interfered Work Past 24 Hours at Week 16 from Baseline			
n	61	71	
Mean (SD)	-0.4 (2.72)	-1.0 (2.57)	
Median	0.0	-1.0	
Q1, Q3	-2.0, 1.0	-3.0, 0.0	
Min, Max	-6.0, 8.0	-9.0, 6.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn25-db.pdf 29AUG2023: 9:43

Table 2.5925: Analysis of MPN-SAF Mean Questionnaire Item #25 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	73	76	
n [2]	61	71	
MMRM: Least Squares Mean [SE] (95% CI)	0.00 [0.31] (-0.61, 0.62)	-0.62 [0.29] (-1.20, -0.04)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.63 [0.39] (-0.15, 1.40)		
MMRM: P-value	0.11		
Corrected Hedges' g (95% CI)	0.254 (-0.089, 0.598)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.19		
Percent Change in Interfered Work Past 24 Hours at Week 16 from Baseline			
n	51	59	
Mean (SD)	-6.3 (68.65)	-20.1 (81.07)	
Median	-12.5	-33.3	
Q1, Q3	-57.1, 11.1	-60.0, 0.0	
Min, Max	-100.0, 200.0	-100.0, 300.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	60	63	
n [2]	51	59	
MMRM: Least Squares Mean [SE] (95% CI)	-3.13 [10.90] (-24.72, 18.46)	-14.02 [10.18] (-34.18, 6.13)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	10.89 [13.94] (-16.73, 38.51)		
MMRM: P-value	0.44		
Corrected Hedges' g (95% CI)	0.139 (-0.237, 0.514)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.091		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5925: Analysis of MPN-SAF Mean Questionnaire Item #25 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
BFI0107 - Interfered Work Past 24 Hours at Week 20			
n	64	83	
Mean (SD)	3.3 (2.81)	2.9 (2.89)	
Median	3.0	3.0	
Q1, Q3	1.0, 5.0	0.0, 4.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	74%	88%	
Number of Subjects in Risk	74	90	
Return Rate in Risk (%)	86%	92%	
Change in Interfered Work Past 24 Hours at Week 20 from Baseline			
n	59	69	
Mean (SD)	-0.7 (2.34)	-1.0 (2.70)	
Median	-1.0	-1.0	
Q1, Q3	-2.0, 1.0	-2.0, 0.0	
Min, Max	-6.0, 5.0	-8.0, 8.0	
Difference in Change from Baseline at Week 20			
n [1]	73	76	
n [2]	59	69	
MMRM: Least Squares Mean [SE] (95% CI)	-0.21 [0.31] (-0.82, 0.41)		-0.70 [0.29] (-1.27, -0.12)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.49 [0.39] (-0.28, 1.26)		
MMRM: P-value	0.21		
Corrected Hedges' g (95% CI)	0.203 (-0.145, 0.551)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.42		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5925: Analysis of MPN-SAF Mean Questionnaire Item #25 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Interfered Work Past 24 Hours at Week 20 from Baseline		
n	49	57
Mean (SD)	-12.6 (67.69)	-13.4 (102.85)
Median	-25.0	-33.3
Q1, Q3	-55.6, 20.0	-66.7, 0.0
Min, Max	-100.0, 200.0	-100.0, 500.0
Difference in Percent Change from Baseline at Week 20		
n [1]	60	63
n [2]	49	57
MMRM: Least Squares Mean [SE] (95% CI)	-5.40 [12.64] (-30.45, 19.64)	-7.37 [11.80] (-30.74, 16.00)
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.97 [16.46] (-30.64, 34.58)	
MMRM: P-value	0.90	
Corrected Hedges' g (95% CI)	0.022 (-0.360, 0.404)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.35	
BFI0107 - Interfered Work Past 24 Hours at Week 24		
n	65	82
Mean (SD)	3.1 (2.51)	2.7 (2.43)
Median	3.0	2.5
Q1, Q3	1.0, 5.0	0.0, 4.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	76%	87%
Number of Subjects in Risk	70	87
Return Rate in Risk (%)	93%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5925: Analysis of MPN-SAF Mean Questionnaire Item #25 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Interfered Work Past 24 Hours at Week 24 from Baseline			
n	59	68	
Mean (SD)	-0.8 (2.74)	-1.2 (2.39)	
Median	0.0	-1.0	
Q1, Q3	-3.0, 1.0	-3.0, 0.0	
Min, Max	-7.0, 8.0	-7.0, 5.0	
Difference in Change from Baseline at Week 24			
n [1]	73	76	
n [2]	59	68	
MMRM: Least Squares Mean [SE] (95% CI)	-0.33 [0.29] (-0.90, 0.24)	-0.90 [0.27] (-1.43, -0.36)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.57 [0.36] (-0.14, 1.27)		
MMRM: P-value	0.11		
Corrected Hedges' g (95% CI)	0.255 (-0.095, 0.605)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.16		
Percent Change in Interfered Work Past 24 Hours at Week 24 from Baseline			
n	48	55	
Mean (SD)	-19.4 (51.27)	-28.0 (91.55)	
Median	-19.6	-42.9	
Q1, Q3	-60.0, 12.7	-71.4, 0.0	
Min, Max	-100.0, 100.0	-100.0, 500.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5925: Analysis of MPN-SAF Mean Questionnaire Item #25 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	60	63	
n [2]	48	55	
MMRM: Least Squares Mean [SE] (95% CI)	-10.65 [11.01] (-32.45, 11.15)		-22.61 [10.28] (-42.97, -2.25)
MMRM: Least Squares Mean Difference [SE] (95% CI)	11.96 [14.10] (-15.97, 39.88)		
MMRM: P-value	0.40		
Corrected Hedges' g (95% CI)	0.156 (-0.232, 0.543)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.024		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

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Table 2.5926: Analysis of MPN-SAF Mean Questionnaire Item #26 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
BFI0108 - Interfered Relations Past 24 Hours at Baseline		
n	77	76
Mean (SD)	3.1 (2.86)	3.0 (2.82)
Median	3.0	2.5
Q1, Q3	0.0, 5.0	0.5, 5.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
BFI0108 - Interfered Relations Past 24 Hours at Week 4		
n	76	90
Mean (SD)	2.4 (2.34)	2.1 (2.38)
Median	2.0	1.0
Q1, Q3	0.0, 4.0	0.0, 3.0
Min, Max	0.0, 10.0	0.0, 8.0
Return Rate (%)	88%	96%
Number of Subjects in Risk	82	94
Return Rate in Risk (%)	93%	96%
Change in Interfered Relations Past 24 Hours at Week 4 from Baseline		
n	71	75
Mean (SD)	-0.6 (2.29)	-1.0 (2.47)
Median	0.0	-1.0
Q1, Q3	-2.0, 0.0	-2.0, 0.0
Min, Max	-6.0, 5.0	-9.0, 4.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5926: Analysis of MPN-SAF Mean Questionnaire Item #26 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	73	76	
n [2]	71	75	
MMRM: Least Squares Mean [SE] (95% CI)	-0.21 [0.25] (-0.71, 0.29)	-0.65 [0.24] (-1.13, -0.18)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.44 [0.31] (-0.18, 1.06)		
MMRM: P-value	0.16		
Corrected Hedges' g (95% CI)	0.208 (-0.117, 0.534)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.32		
Percent Change in Interfered Relations Past 24 Hours at Week 4 from Baseline			
n	51	57	
Mean (SD)	-10.3 (83.52)	-37.8 (61.01)	
Median	-25.0	-44.4	
Q1, Q3	-57.1, 0.0	-100.0, 0.0	
Min, Max	-100.0, 300.0	-100.0, 150.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	53	57	
n [2]	51	57	
MMRM: Least Squares Mean [SE] (95% CI)	-3.75 [10.93] (-25.42, 17.92)	-35.40 [10.28] (-55.78, -15.01)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	31.64 [14.29] (3.31, 59.98)		
MMRM: P-value	0.029		
Corrected Hedges' g (95% CI)	0.404 (0.022, 0.785)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.047		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5926: Analysis of MPN-SAF Mean Questionnaire Item #26 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
BFI0108 - Interfered Relations Past 24 Hours at Week 8			
n	70	86	
Mean (SD)	2.5 (2.64)	2.0 (2.32)	
Median	2.0	1.0	
Q1, Q3	0.0, 4.0	0.0, 3.0	
Min, Max	0.0, 9.0	0.0, 9.0	
Return Rate (%)	81%	91%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	91%	
Change in Interfered Relations Past 24 Hours at Week 8 from Baseline			
n	65	73	
Mean (SD)	-0.5 (2.51)	-0.9 (2.37)	
Median	-1.0	0.0	
Q1, Q3	-2.0, 1.0	-2.0, 0.0	
Min, Max	-6.0, 5.0	-9.0, 3.0	
Difference in Change from Baseline at Week 8			
n [1]	73	76	
n [2]	65	73	
MMRM: Least Squares Mean [SE] (95% CI)	0.01 [0.27] (-0.52, 0.55)	-0.61 [0.25] (-1.11, -0.11)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.62 [0.34] (-0.05, 1.29)		
MMRM: P-value	0.068		
Corrected Hedges' g (95% CI)	0.284 (-0.052, 0.620)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.41		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5926: Analysis of MPN-SAF Mean Questionnaire Item #26 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Interfered Relations Past 24 Hours at Week 8 from Baseline			
n	47	55	
Mean (SD)	-27.4 (71.30)	-36.5 (54.73)	
Median	-50.0	-40.0	
Q1, Q3	-75.0, 0.0	-100.0, 0.0	
Min, Max	-100.0, 200.0	-100.0, 100.0	
Difference in Percent Change from Baseline at Week 8			
n [1]	53	57	
n [2]	47	55	
MMRM: Least Squares Mean [SE] (95% CI)	-16.20 [9.33] (-34.70, 2.30)	-34.26 [8.54] (-51.20, -17.32)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	18.07 [11.80] (-5.35, 41.48)		
MMRM: P-value	0.13		
Corrected Hedges' g (95% CI)	0.282 (-0.109, 0.673)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.30		
BFI0108 - Interfered Relations Past 24 Hours at Week 12			
n	71	89	
Mean (SD)	2.6 (2.42)	2.4 (2.55)	
Median	2.0	2.0	
Q1, Q3	0.0, 4.0	0.0, 4.0	
Min, Max	0.0, 9.0	0.0, 10.0	
Return Rate (%)	83%	95%	
Number of Subjects in Risk	76	94	
Return Rate in Risk (%)	93%	95%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5926: Analysis of MPN-SAF Mean Questionnaire Item #26 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Change in Interfered Relations Past 24 Hours at Week 12 from Baseline		
n	65	74
Mean (SD)	-0.2 (2.66)	-0.6 (2.53)
Median	0.0	0.0
Q1, Q3	-2.0, 1.0	-2.0, 1.0
Min, Max	-7.0, 8.0	-9.0, 4.0
Difference in Change from Baseline at Week 12		
n [1]	73	76
n [2]	65	74
MMRM: Least Squares Mean [SE] (95% CI)	0.23 [0.28] (-0.33, 0.79)	-0.22 [0.26] (-0.74, 0.31)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.45 [0.35] (-0.25, 1.14)	
MMRM: P-value	0.21	
Corrected Hedges' g (95% CI)	0.196 (-0.138, 0.530)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.53	
Percent Change in Interfered Relations Past 24 Hours at Week 12 from Baseline		
n	45	55
Mean (SD)	-4.4 (96.81)	-21.3 (70.29)
Median	-25.0	-20.0
Q1, Q3	-62.5, 20.0	-100.0, 25.0
Min, Max	-100.0, 400.0	-100.0, 200.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5926: Analysis of MPN-SAF Mean Questionnaire Item #26 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	53	57	
n [2]	45	55	
MMRM: Least Squares Mean [SE] (95% CI)	1.33 [12.43] (-23.32, 25.98)	-17.96 [11.48] (-40.73, 4.80)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	19.29 [16.28] (-13.01, 51.59)		
MMRM: P-value	0.24		
Corrected Hedges' g (95% CI)	0.227 (-0.168, 0.622)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.33		
BFI0108 - Interfered Relations Past 24 Hours at Week 16			
n	67	83	
Mean (SD)	2.6 (2.43)	2.2 (2.44)	
Median	3.0	1.0	
Q1, Q3	0.0, 4.0	0.0, 4.0	
Min, Max	0.0, 10.0	0.0, 8.0	
Return Rate (%)	78%	88%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	89%	91%	
Change in Interfered Relations Past 24 Hours at Week 16 from Baseline			
n	61	71	
Mean (SD)	-0.3 (2.76)	-0.7 (2.58)	
Median	0.0	0.0	
Q1, Q3	-2.0, 1.0	-2.0, 1.0	
Min, Max	-7.0, 8.0	-9.0, 5.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5926: Analysis of MPN-SAF Mean Questionnaire Item #26 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	73	76	
n [2]	61	71	
MMRM: Least Squares Mean [SE] (95% CI)	0.21 [0.28] (-0.35, 0.77)	-0.40 [0.26] (-0.93, 0.12)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.61 [0.36] (-0.10, 1.31)		
MMRM: P-value	0.089		
Corrected Hedges' g (95% CI)	0.272 (-0.071, 0.616)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.34		
Percent Change in Interfered Relations Past 24 Hours at Week 16 from Baseline			
n	43	52	
Mean (SD)	-5.1 (81.77)	-24.6 (79.05)	
Median	-22.2	-40.0	
Q1, Q3	-66.7, 33.3	-100.0, 0.0	
Min, Max	-100.0, 200.0	-100.0, 300.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	53	57	
n [2]	43	52	
MMRM: Least Squares Mean [SE] (95% CI)	0.71 [11.76] (-22.61, 24.03)	-23.03 [10.73] (-44.32, -1.75)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	23.74 [15.25] (-6.51, 54.00)		
MMRM: P-value	0.12		
Corrected Hedges' g (95% CI)	0.305 (-0.102, 0.711)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.050		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5926: Analysis of MPN-SAF Mean Questionnaire Item #26 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
BFI0108 - Interfered Relations Past 24 Hours at Week 20			
n	64	83	
Mean (SD)	2.5 (2.91)	2.3 (2.47)	
Median	2.0	2.0	
Q1, Q3	0.0, 4.0	0.0, 3.0	
Min, Max	0.0, 10.0	0.0, 9.0	
Return Rate (%)	74%	88%	
Number of Subjects in Risk	74	90	
Return Rate in Risk (%)	86%	92%	
Change in Interfered Relations Past 24 Hours at Week 20 from Baseline			
n	59	69	
Mean (SD)	-0.3 (2.73)	-0.7 (2.61)	
Median	0.0	0.0	
Q1, Q3	-2.0, 1.0	-2.0, 1.0	
Min, Max	-7.0, 10.0	-9.0, 7.0	
Difference in Change from Baseline at Week 20			
n [1]	73	76	
n [2]	59	69	
MMRM: Least Squares Mean [SE] (95% CI)	0.12 [0.30] (-0.47, 0.72)	-0.35 [0.28] (-0.91, 0.20)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.48 [0.38] (-0.28, 1.23)		
MMRM: P-value	0.21		
Corrected Hedges' g (95% CI)	0.203 (-0.145, 0.552)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.23		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5926: Analysis of MPN-SAF Mean Questionnaire Item #26 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Interfered Relations Past 24 Hours at Week 20 from Baseline			
n	42	52	
Mean (SD)	-1.0 (90.90)	-32.7 (59.66)	
Median	-17.4	-45.0	
Q1, Q3	-71.4, 50.0	-100.0, 0.0	
Min, Max	-100.0, 300.0	-100.0, 100.0	
Difference in Percent Change from Baseline at Week 20			
n [1]	53	57	
n [2]	42	52	
MMRM: Least Squares Mean [SE] (95% CI)	5.80 [11.36] (-16.73, 28.33)		-29.61 [10.37] (-50.17, -9.05)
MMRM: Least Squares Mean Difference [SE] (95% CI)	35.41 [14.68] (6.31, 64.52)		
MMRM: P-value	0.018		
Corrected Hedges' g (95% CI)	0.473 (0.061, 0.885)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.071		
BFI0108 - Interfered Relations Past 24 Hours at Week 24			
n	65	82	
Mean (SD)	2.1 (2.16)	2.0 (2.42)	
Median	1.0	1.0	
Q1, Q3	0.0, 3.0	0.0, 3.0	
Min, Max	0.0, 8.0	0.0, 10.0	
Return Rate (%)	76%	87%	
Number of Subjects in Risk	70	87	
Return Rate in Risk (%)	93%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5926: Analysis of MPN-SAF Mean Questionnaire Item #26 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Change in Interfered Relations Past 24 Hours at Week 24 from Baseline		
n	59	68
Mean (SD)	-0.6 (2.20)	-0.7 (2.56)
Median	0.0	-1.0
Q1, Q3	-2.0, 1.0	-1.5, 0.5
Min, Max	-7.0, 4.0	-9.0, 5.0
Difference in Change from Baseline at Week 24		
n [1]	73	76
n [2]	59	68
MMRM: Least Squares Mean [SE] (95% CI)	-0.17 [0.26] (-0.68, 0.35)	-0.45 [0.24] (-0.93, 0.03)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.28 [0.32] (-0.36, 0.92)	
MMRM: P-value	0.39	
Corrected Hedges' g (95% CI)	0.139 (-0.210, 0.488)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.23	
Percent Change in Interfered Relations Past 24 Hours at Week 24 from Baseline		
n	40	49
Mean (SD)	-19.0 (59.45)	-35.6 (62.01)
Median	-31.0	-40.0
Q1, Q3	-66.7, 12.5	-100.0, 0.0
Min, Max	-100.0, 100.0	-100.0, 133.3

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5926: Analysis of MPN-SAF Mean Questionnaire Item #26 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	53	57	
n [2]	40	49	
MMRM: Least Squares Mean [SE] (95% CI)	-9.52 [9.38] (-28.12, 9.09)		-31.67 [8.58] (-48.68, -14.65)
MMRM: Least Squares Mean Difference [SE] (95% CI)	22.15 [11.85] (-1.35, 45.65)		
MMRM: P-value	0.064		
Corrected Hedges' g (95% CI)	0.368 (-0.053, 0.789)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.029		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5927: Analysis of MPN-SAF Mean Questionnaire Item #27 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
BFI0109 - Interfered Enjoyment Past 24 Hours at Baseline		
n	77	76
Mean (SD)	4.1 (3.11)	4.0 (3.13)
Median	4.0	4.0
Q1, Q3	1.0, 6.0	1.0, 6.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
BFI0109 - Interfered Enjoyment Past 24 Hours at Week 4		
n	76	90
Mean (SD)	3.1 (2.74)	2.5 (2.68)
Median	2.0	1.5
Q1, Q3	1.0, 4.5	0.0, 4.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	88%	96%
Number of Subjects in Risk	82	94
Return Rate in Risk (%)	93%	96%
Change in Interfered Enjoyment Past 24 Hours at Week 4 from Baseline		
n	71	75
Mean (SD)	-0.8 (2.48)	-1.5 (2.50)
Median	0.0	-1.0
Q1, Q3	-2.0, 0.0	-3.0, 0.0
Min, Max	-6.0, 4.0	-9.0, 4.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5927: Analysis of MPN-SAF Mean Questionnaire Item #27 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	73	76	
n [2]	71	75	
MMRM: Least Squares Mean [SE] (95% CI)	-0.47 [0.27] (-1.01, 0.07)	-1.24 [0.26] (-1.76, -0.73)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.77 [0.34] (0.10, 1.45)		
MMRM: P-value	0.025		
Corrected Hedges' g (95% CI)	0.338 (0.011, 0.664)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.099		
Percent Change in Interfered Enjoyment Past 24 Hours at Week 4 from Baseline			
n	58	60	
Mean (SD)	-7.4 (72.19)	-33.5 (73.10)	
Median	-20.0	-38.8	
Q1, Q3	-50.0, 0.0	-77.5, 0.0	
Min, Max	-100.0, 300.0	-100.0, 400.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	60	61	
n [2]	58	60	
MMRM: Least Squares Mean [SE] (95% CI)	-3.62 [10.34] (-24.12, 16.87)	-30.20 [10.02] (-50.04, -10.35)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	26.57 [13.30] (0.22, 52.92)		
MMRM: P-value	0.048		
Corrected Hedges' g (95% CI)	0.338 (-0.026, 0.701)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.007		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5927: Analysis of MPN-SAF Mean Questionnaire Item #27 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
BFI0109 - Interfered Enjoyment Past 24 Hours at Week 8			
n	70	86	
Mean (SD)	3.3 (2.76)	2.6 (2.71)	
Median	2.5	2.0	
Q1, Q3	1.0, 5.0	0.0, 4.0	
Min, Max	0.0, 10.0	0.0, 9.0	
Return Rate (%)	81%	91%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	91%	
Change in Interfered Enjoyment Past 24 Hours at Week 8 from Baseline			
n	65	73	
Mean (SD)	-0.6 (2.78)	-1.3 (2.40)	
Median	-1.0	-1.0	
Q1, Q3	-2.0, 1.0	-2.0, 0.0	
Min, Max	-6.0, 8.0	-9.0, 4.0	
Difference in Change from Baseline at Week 8			
n [1]	73	76	
n [2]	65	73	
MMRM: Least Squares Mean [SE] (95% CI)		-0.22 [0.29] (-0.78, 0.35)	-1.11 [0.27] (-1.64, -0.58)
MMRM: Least Squares Mean Difference [SE] (95% CI)		0.89 [0.36] (0.18, 1.61)	
MMRM: P-value	0.014		
Corrected Hedges' g (95% CI)	0.385 (0.048, 0.723)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.23		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5927: Analysis of MPN-SAF Mean Questionnaire Item #27 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Interfered Enjoyment Past 24 Hours at Week 8 from Baseline		
n	53	58
Mean (SD)	-12.6 (85.14)	-31.4 (58.12)
Median	-25.0	-33.3
Q1, Q3	-66.7, 0.0	-75.0, 0.0
Min, Max	-100.0, 400.0	-100.0, 200.0
Difference in Percent Change from Baseline at Week 8		
n [1]	60	61
n [2]	53	58
MMRM: Least Squares Mean [SE] (95% CI)	-8.74 [10.54] (-29.61, 12.14)	-29.77 [10.03] (-49.64, -9.91)
MMRM: Least Squares Mean Difference [SE] (95% CI)	21.04 [13.46] (-5.63, 47.71)	
MMRM: P-value	0.12	
Corrected Hedges' g (95% CI)	0.273 (-0.101, 0.647)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.21	
BFI0109 - Interfered Enjoyment Past 24 Hours at Week 12		
n	71	89
Mean (SD)	3.2 (2.51)	2.5 (2.55)
Median	3.0	2.0
Q1, Q3	1.0, 5.0	0.0, 4.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	83%	95%
Number of Subjects in Risk	76	94
Return Rate in Risk (%)	93%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5927: Analysis of MPN-SAF Mean Questionnaire Item #27 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Interfered Enjoyment Past 24 Hours at Week 12 from Baseline			
n	65	74	
Mean (SD)	-0.5 (2.69)	-1.3 (2.33)	
Median	0.0	-1.0	
Q1, Q3	-2.0, 1.0	-2.0, 0.0	
Min, Max	-6.0, 8.0	-9.0, 3.0	
Difference in Change from Baseline at Week 12			
n [1]	73	76	
n [2]	65	74	
MMRM: Least Squares Mean [SE] (95% CI)	-0.10 [0.27] (-0.63, 0.43)	-1.10 [0.25] (-1.60, -0.61)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.00 [0.33] (0.35, 1.65)		
MMRM: P-value	0.003		
Corrected Hedges' g (95% CI)	0.462 (0.125, 0.800)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.091		
Percent Change in Interfered Enjoyment Past 24 Hours at Week 12 from Baseline			
n	53	59	
Mean (SD)	-8.4 (70.09)	-29.7 (69.51)	
Median	-20.0	-33.3	
Q1, Q3	-50.0, 0.0	-75.0, 0.0	
Min, Max	-100.0, 200.0	-100.0, 300.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5927: Analysis of MPN-SAF Mean Questionnaire Item #27 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	60	61	
n [2]	53	59	
MMRM: Least Squares Mean [SE] (95% CI)	-4.39 [9.92] (-24.04, 15.26)		-25.87 [9.40] (-44.49, -7.25)
MMRM: Least Squares Mean Difference [SE] (95% CI)	21.48 [12.51] (-3.30, 46.25)		
MMRM: P-value	0.089		
Corrected Hedges' g (95% CI)	0.295 (-0.078, 0.668)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.050		
BFI0109 - Interfered Enjoyment Past 24 Hours at Week 16			
n	67	83	
Mean (SD)	3.1 (2.82)	2.5 (2.65)	
Median	3.0	2.0	
Q1, Q3	0.0, 5.0	0.0, 4.0	
Min, Max	0.0, 10.0	0.0, 9.0	
Return Rate (%)	78%	88%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	89%	91%	
Change in Interfered Enjoyment Past 24 Hours at Week 16 from Baseline			
n	61	71	
Mean (SD)	-0.7 (2.81)	-1.4 (2.41)	
Median	0.0	-1.0	
Q1, Q3	-2.0, 1.0	-3.0, 0.0	
Min, Max	-8.0, 8.0	-9.0, 4.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.5927: Analysis of MPN-SAF Mean Questionnaire Item #27 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	73	76	
n [2]	61	71	
MMRM: Least Squares Mean [SE] (95% CI)	-0.23 [0.30] (-0.82, 0.35)	-1.19 [0.28] (-1.73, -0.64)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.96 [0.37] (0.22, 1.69)		
MMRM: P-value	0.011		
Corrected Hedges' g (95% CI)	0.410 (0.064, 0.756)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.053		
Percent Change in Interfered Enjoyment Past 24 Hours at Week 16 from Baseline			
n	51	57	
Mean (SD)	-11.7 (70.45)	-30.7 (67.83)	
Median	-14.3	-44.4	
Q1, Q3	-66.7, 33.3	-71.4, 0.0	
Min, Max	-100.0, 200.0	-100.0, 300.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	60	61	
n [2]	51	57	
MMRM: Least Squares Mean [SE] (95% CI)	-9.14 [9.75] (-28.46, 10.19)	-27.36 [9.26] (-45.70, -9.01)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	18.22 [12.27] (-6.09, 42.53)		
MMRM: P-value	0.14		
Corrected Hedges' g (95% CI)	0.259 (-0.120, 0.639)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.13		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.5927: Analysis of MPN-SAF Mean Questionnaire Item #27 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
BFI0109 - Interfered Enjoyment Past 24 Hours at Week 20			
n	64	83	
Mean (SD)	3.2 (2.87)	2.6 (2.76)	
Median	3.0	2.0	
Q1, Q3	1.0, 5.0	0.0, 4.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	74%	88%	
Number of Subjects in Risk	74	90	
Return Rate in Risk (%)	86%	92%	
Change in Interfered Enjoyment Past 24 Hours at Week 20 from Baseline			
n	59	69	
Mean (SD)	-0.8 (2.27)	-1.3 (2.33)	
Median	0.0	-1.0	
Q1, Q3	-2.0, 1.0	-3.0, 0.0	
Min, Max	-8.0, 5.0	-9.0, 4.0	
Difference in Change from Baseline at Week 20			
n [1]	73	76	
n [2]	59	69	
MMRM: Least Squares Mean [SE] (95% CI)	-0.15 [0.28] (-0.71, 0.40)	-1.11 [0.26] (-1.62, -0.60)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.96 [0.35] (0.27, 1.64)		
MMRM: P-value	0.006		
Corrected Hedges' g (95% CI)	0.443 (0.091, 0.795)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.14		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn27-db.pdf 29AUG2023: 9:44

Table 2.5927: Analysis of MPN-SAF Mean Questionnaire Item #27 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Interfered Enjoyment Past 24 Hours at Week 20 from Baseline		
n	50	55
Mean (SD)	-11.6 (76.42)	-35.4 (58.69)
Median	-25.0	-40.0
Q1, Q3	-60.0, 20.0	-75.0, 0.0
Min, Max	-100.0, 300.0	-100.0, 200.0
Difference in Percent Change from Baseline at Week 20		
n [1]	60	61
n [2]	50	55
MMRM: Least Squares Mean [SE] (95% CI)	-0.20 [10.42] (-20.85, 20.45)	-31.54 [9.93] (-51.21, -11.87)
MMRM: Least Squares Mean Difference [SE] (95% CI)	31.34 [13.30] (4.99, 57.68)	
MMRM: P-value	0.020	
Corrected Hedges' g (95% CI)	0.422 (0.035, 0.810)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.11	
BFI0109 - Interfered Enjoyment Past 24 Hours at Week 24		
n	65	82
Mean (SD)	2.7 (2.48)	2.2 (2.48)
Median	2.0	1.5
Q1, Q3	1.0, 4.0	0.0, 4.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	76%	87%
Number of Subjects in Risk	70	87
Return Rate in Risk (%)	93%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn27-db.pdf 29AUG2023: 9:44

Table 2.5927: Analysis of MPN-SAF Mean Questionnaire Item #27 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Interfered Enjoyment Past 24 Hours at Week 24 from Baseline			
n	59	68	
Mean (SD)	-1.0 (2.73)	-1.5 (2.38)	
Median	-1.0	-1.0	
Q1, Q3	-3.0, 1.0	-3.0, 0.0	
Min, Max	-8.0, 5.0	-9.0, 3.0	
Difference in Change from Baseline at Week 24			
n [1]	73	76	
n [2]	59	68	
MMRM: Least Squares Mean [SE] (95% CI)	-0.46 [0.28] (-1.00, 0.09)	-1.25 [0.26] (-1.76, -0.74)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.80 [0.34] (0.12, 1.47)		
MMRM: P-value	0.022		
Corrected Hedges' g (95% CI)	0.373 (0.021, 0.724)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.21		
Percent Change in Interfered Enjoyment Past 24 Hours at Week 24 from Baseline			
n	48	53	
Mean (SD)	-11.2 (95.62)	-35.5 (56.30)	
Median	-29.2	-50.0	
Q1, Q3	-66.7, 0.0	-80.0, 0.0	
Min, Max	-100.0, 500.0	-100.0, 100.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5927: Analysis of MPN-SAF Mean Questionnaire Item #27 Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	**60**	**61**	
n [2]	**48**	**53**	
MMRM: Least Squares Mean [SE] (95% CI)		**-5.66 [11.05] (-27.56, 16.24)**	**-29.64 [10.56] (-50.56, -8.73)**
MMRM: Least Squares Mean Difference [SE] (95% CI)		**23.99 [14.25] (-4.24, 52.22)**	
MMRM: P-value	**0.095**		
Corrected Hedges' g (95% CI)	**0.310 (-0.083, 0.703)**		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	**0.095**		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5801: Analysis of MPN-SAF Mean Symptom Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
MPNSAF - MPN-SAF at Baseline		
n	77	76
Mean (SD)	3.0 (2.02)	3.0 (1.85)
Median	3.0	2.9
Q1, Q3	1.4, 4.3	1.5, 4.3
Min, Max	0.0, 7.6	0.1, 7.1
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
MPNSAF - MPN-SAF at Week 4		
n	76	90
Mean (SD)	2.4 (1.85)	2.2 (1.72)
Median	1.8	1.8
Q1, Q3	1.1, 3.7	0.7, 3.1
Min, Max	0.0, 9.2	0.0, 6.6
Return Rate (%)	88%	96%
Number of Subjects in Risk	82	94
Return Rate in Risk (%)	93%	96%
Change in MPN-SAF at Week 4 from Baseline		
n	71	75
Mean (SD)	-0.6 (1.33)	-0.8 (1.29)
Median	-0.4	-0.7
Q1, Q3	-1.5, 0.4	-1.4, -0.1
Min, Max	-3.7, 3.1	-4.4, 2.9

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn-db.pdf 29AUG2023: 9:37

Table 2.5801: Analysis of MPN-SAF Mean Symptom Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	73	76	
n [2]	71	75	
MMRM: Least Squares Mean [SE] (95% CI)	-0.22 [0.16] (-0.53, 0.09)	-0.59 [0.15] (-0.88, -0.29)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.37 [0.19] (-0.01, 0.75)		
MMRM: P-value	0.059		
Corrected Hedges' g (95% CI)	0.277 (-0.049, 0.603)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.27		
Percent Change in MPN-SAF at Week 4 from Baseline			
n	71	75	
Mean (SD)	13.0 (134.32)	-26.5 (49.70)	
Median	-20.8	-31.8	
Q1, Q3	-47.3, 16.7	-63.3, -6.3	
Min, Max	-100.0, 750.0	-92.9, 250.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	73	76	
n [2]	71	75	
MMRM: Least Squares Mean [SE] (95% CI)	21.70 [12.46] (-2.94, 46.33)	-16.75 [12.01] (-40.49, 7.00)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	38.44 [16.11] (6.59, 70.30)		
MMRM: P-value	0.018		
Corrected Hedges' g (95% CI)	0.366 (0.039, 0.693)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.043		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.5801: Analysis of MPN-SAF Mean Symptom Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPNSAF - MPN-SAF at Week 8			
n	70	86	
Mean (SD)	2.6 (1.91)	2.1 (1.59)	
Median	2.0	1.8	
Q1, Q3	1.2, 4.0	0.7, 3.1	
Min, Max	0.0, 8.4	0.0, 5.5	
Return Rate (%)	81%	91%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	91%	
Change in MPN-SAF at Week 8 from Baseline			
n	65	73	
Mean (SD)	-0.4 (1.41)	-0.9 (1.41)	
Median	-0.4	-0.6	
Q1, Q3	-1.2, 0.3	-1.5, 0.0	
Min, Max	-3.5, 4.1	-5.6, 1.8	
Difference in Change from Baseline at Week 8			
n [1]	73	76	
n [2]	65	73	
MMRM: Least Squares Mean [SE] (95% CI)	0.05 [0.17] (-0.30, 0.39)	-0.64 [0.17] (-0.97, -0.32)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.69 [0.22] (0.26, 1.12)		
MMRM: P-value	0.002		
Corrected Hedges' g (95% CI)	0.487 (0.148, 0.826)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.23		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5801: Analysis of MPN-SAF Mean Symptom Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in MPN-SAF at Week 8 from Baseline		
n	65	73
Mean (SD)	132.1 (758.24)	-20.5 (70.91)
Median	-15.2	-27.3
Q1, Q3	-47.3, 14.3	-65.3, 1.6
Min, Max	-93.3, 5600.0	-95.0, 450.0
Difference in Percent Change from Baseline at Week 8		
n [1]	73	76
n [2]	65	73
MMRM: Least Squares Mean [SE] (95% CI)	151.34 [62.09] (28.60, 274.08)	-13.15 [60.31] (-132.38, 106.08)
MMRM: Least Squares Mean Difference [SE] (95% CI)	164.49 [86.31] (-6.14, 335.12)	
MMRM: P-value	0.059	
Corrected Hedges' g (95% CI)	0.322 (-0.015, 0.658)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.044	
MPNSAF - MPN-SAF at Week 12		
n	71	89
Mean (SD)	2.5 (1.77)	2.1 (1.55)
Median	2.1	1.7
Q1, Q3	1.1, 3.2	0.8, 3.3
Min, Max	0.2, 8.3	0.1, 5.7
Return Rate (%)	83%	95%
Number of Subjects in Risk	76	94
Return Rate in Risk (%)	93%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5801: Analysis of MPN-SAF Mean Symptom Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in MPN-SAF at Week 12 from Baseline			
n	65	74	
Mean (SD)	-0.4 (1.53)	-0.9 (1.29)	
Median	-0.2	-0.7	
Q1, Q3	-1.2, 0.4	-1.4, -0.1	
Min, Max	-5.2, 3.3	-4.7, 1.5	
Difference in Change from Baseline at Week 12			
n [1]	73	76	
n [2]	65	74	
MMRM: Least Squares Mean [SE] (95% CI)	0.00 [0.17] (-0.33, 0.33)	-0.59 [0.15] (-0.90, -0.29)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.59 [0.20] (0.20, 0.99)		
MMRM: P-value	0.004		
Corrected Hedges' g (95% CI)	0.444 (0.106, 0.781)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.017		
Percent Change in MPN-SAF at Week 12 from Baseline			
n	65	74	
Mean (SD)	56.5 (252.69)	-22.1 (59.72)	
Median	-10.0	-26.5	
Q1, Q3	-41.1, 29.6	-57.8, -10.5	
Min, Max	-77.1, 1250.0	-97.5, 350.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5801: Analysis of MPN-SAF Mean Symptom Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	73	76	
n [2]	65	74	
MMRM: Least Squares Mean [SE] (95% CI)	62.39 [20.94] (21.00, 103.79)		-11.12 [20.18] (-51.00, 28.77)
MMRM: Least Squares Mean Difference [SE] (95% CI)	73.51 [28.38] (17.42, 129.61)		
MMRM: P-value	0.011		
Corrected Hedges' g (95% CI)	0.427 (0.090, 0.764)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.007		
MPNSAF - MPN-SAF at Week 16			
n	67	83	
Mean (SD)	2.5 (1.99)	2.1 (1.64)	
Median	2.1	2.0	
Q1, Q3	0.7, 3.5	0.7, 3.3	
Min, Max	0.0, 9.3	0.0, 6.3	
Return Rate (%)	78%	88%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	89%	91%	
Change in MPN-SAF at Week 16 from Baseline			
n	61	71	
Mean (SD)	-0.4 (1.57)	-0.9 (1.41)	
Median	-0.3	-0.7	
Q1, Q3	-1.3, 0.3	-1.7, 0.0	
Min, Max	-6.2, 3.0	-5.7, 1.7	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5801: Analysis of MPN-SAF Mean Symptom Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	73	76	
n [2]	61	71	
MMRM: Least Squares Mean [SE] (95% CI)	0.02 [0.18] (-0.35, 0.38)	-0.58 [0.17] (-0.92, -0.25)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.60 [0.23] (0.15, 1.05)		
MMRM: P-value	0.010		
Corrected Hedges' g (95% CI)	0.415 (0.069, 0.761)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.062		
Percent Change in MPN-SAF at Week 16 from Baseline			
n	61	71	
Mean (SD)	45.5 (360.10)	-25.9 (48.64)	
Median	-20.0	-36.7	
Q1, Q3	-44.8, 14.6	-54.7, 0.0	
Min, Max	-100.0, 2666.7	-98.7, 175.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	73	76	
n [2]	61	71	
MMRM: Least Squares Mean [SE] (95% CI)	114.30 [46.48] (22.42, 206.17)	-14.59 [44.83] (-103.21, 74.03)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	128.89 [64.25] (1.87, 255.90)		
MMRM: P-value	0.047		
Corrected Hedges' g (95% CI)	0.345 (0.001, 0.690)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.058		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn-db.pdf 29AUG2023: 9:37

Table 2.5801: Analysis of MPN-SAF Mean Symptom Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
MPNSAF - MPN-SAF at Week 20			
n	64	83	
Mean (SD)	2.5 (2.09)	2.1 (1.58)	
Median	1.9	1.7	
Q1, Q3	1.0, 3.4	0.7, 3.1	
Min, Max	0.1, 9.3	0.0, 7.0	
Return Rate (%)	74%	88%	
Number of Subjects in Risk	74	90	
Return Rate in Risk (%)	86%	92%	
Change in MPN-SAF at Week 20 from Baseline			
n	59	69	
Mean (SD)	-0.4 (1.59)	-0.9 (1.41)	
Median	-0.5	-0.7	
Q1, Q3	-1.4, 0.5	-1.5, -0.1	
Min, Max	-6.4, 4.3	-5.6, 2.1	
Difference in Change from Baseline at Week 20			
n [1]	73	76	
n [2]	59	69	
MMRM: Least Squares Mean [SE] (95% CI)	0.02 [0.18] (-0.35, 0.38)	-0.63 [0.17] (-0.97, -0.29)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.64 [0.23] (0.19, 1.10)		
MMRM: P-value	0.006		
Corrected Hedges' g (95% CI)	0.448 (0.097, 0.800)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.091		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5801: Analysis of MPN-SAF Mean Symptom Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in MPN-SAF at Week 20 from Baseline			
n	59	69	
Mean (SD)	28.8 (228.87)	-25.3 (50.36)	
Median	-22.6	-29.1	
Q1, Q3	-47.9, 24.3	-53.5, -6.4	
Min, Max	-90.4, 1400.0	-100.0, 169.7	
Difference in Percent Change from Baseline at Week 20			
n [1]	73	76	
n [2]	59	69	
MMRM: Least Squares Mean [SE] (95% CI)	102.49 [42.55] (18.37, 186.62)	-17.39 [41.31] (-99.06, 64.29)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	119.88 [58.96] (3.33, 236.43)		
MMRM: P-value	0.044		
Corrected Hedges' g (95% CI)	0.355 (0.005, 0.705)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.096		
MPNSAF - MPN-SAF at Week 24			
n	65	82	
Mean (SD)	2.1 (1.71)	1.9 (1.58)	
Median	1.9	1.6	
Q1, Q3	0.9, 2.9	0.6, 2.9	
Min, Max	0.1, 9.2	0.0, 8.5	
Return Rate (%)	76%	87%	
Number of Subjects in Risk	70	87	
Return Rate in Risk (%)	93%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.5801: Analysis of MPN-SAF Mean Symptom Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in MPN-SAF at Week 24 from Baseline			
n	59	68	
Mean (SD)	-0.7 (1.48)	-1.0 (1.28)	
Median	-0.6	-0.8	
Q1, Q3	-1.7, 0.0	-1.7, -0.1	
Min, Max	-6.5, 3.7	-5.5, 1.9	
Difference in Change from Baseline at Week 24			
n [1]	73	76	
n [2]	59	68	
MMRM: Least Squares Mean [SE] (95% CI)	-0.21 [0.17] (-0.54, 0.12)	-0.68 [0.16] (-0.99, -0.37)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.47 [0.20] (0.07, 0.88)		
MMRM: P-value	0.022		
Corrected Hedges' g (95% CI)	0.366 (0.014, 0.717)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.42		
Percent Change in MPN-SAF at Week 24 from Baseline			
n	59	68	
Mean (SD)	36.0 (263.00)	-29.6 (53.26)	
Median	-29.0	-36.0	
Q1, Q3	-53.1, 8.3	-66.3, -9.8	
Min, Max	-86.6, 1500.0	-100.0, 225.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-mpn-db.sas V.03.05 Output file: t-chg-mpn-db.pdf 29AUG2023: 9:37

Table 2.5801: Analysis of MPN-SAF Mean Symptom Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	73	76	
n [2]	59	68	
MMRM: Least Squares Mean [SE] (95% CI)	90.23 [40.12] (10.91, 169.55)	-18.51 [38.96] (-95.54, 58.52)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	108.73 [55.55] (-1.09, 218.56)		
MMRM: P-value	0.052		
Corrected Hedges' g (95% CI)	0.343 (-0.008, 0.694)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.14		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.6101: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #1 at Week 24

Double-blind Phase

ITT-Anemic Analysis Set

	MMB (N = 86)	RUX (N = 94)	Total (N = 180)
MPN0101 - Early Satiety at Week 24			
Responder, n(%)	**17 (19.8%)**	**30 (31.9%)**	**47 (26.1%)**
Unadjusted Inverse Relative Risk (95% CI)	**1.61 (0.96, 2.71)**		
p-value [1]	**0.070**		
Unadjusted Inverse Odds Ratio (95% CI)	**1.90 (0.96, 3.78)**		
p-value [1]	**0.066**		
Unadjusted Absolute Risk Difference (95% CI)	**-0.12 (-0.25, 0.00)**		
Adjusted Inverse Relative Risk (95% CI) [2]	**1.67 (1.00, 2.78)**		
p-value [2]	**0.050**		
Non-Responder, n(%)	**69 (80.2%)**	**64 (68.1%)**	**133 (73.9%)**
Non-missing	**42 (48.8%)**	**38 (40.4%)**	**80 (44.4%)**
Missing	**27 (31.4%)**	**26 (27.7%)**	**53 (29.4%)**

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

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Table 2.6102: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #2 at Week 24

Double-blind Phase

ITT-Anemic Analysis Set

	MMB (N = 86)	RUX (N = 94)	Total (N = 180)
MPN0102 - Abdominal Pain at Week 24			
Responder, n(%)	16 (18.6%)	22 (23.4%)	38 (21.1%)
Unadjusted Inverse Relative Risk (95% CI)	1.26 (0.71, 2.23)		
p-value [1]	0.43		
Unadjusted Inverse Odds Ratio (95% CI)	1.34 (0.65, 2.76)		
p-value [1]	0.43		
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.17, 0.07)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Non-Responder, n(%)	70 (81.4%)	72 (76.6%)	142 (78.9%)
Non-missing	43 (50.0%)	46 (48.9%)	89 (49.4%)
Missing	27 (31.4%)	26 (27.7%)	53 (29.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

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Table 2.6103: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #3 at Week 24
Double-blind Phase
ITT-Anemic Analysis Set

	MMB (N = 86)	RUX (N = 94)	Total (N = 180)
MPN0103 - Abdominal Discomfort at Week 24			
Responder, n(%)	21 (24.4%)	23 (24.5%)	44 (24.4%)
Unadjusted Inverse Relative Risk (95% CI)	1.00 (0.60, 1.68)		
p-value [1]	0.99		
Unadjusted Inverse Odds Ratio (95% CI)	1.00 (0.51, 1.98)		
p-value [1]	0.99		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.13, 0.13)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Non-Responder, n(%)	65 (75.6%)	71 (75.5%)	136 (75.6%)
Non-missing	38 (44.2%)	45 (47.9%)	83 (46.1%)
Missing	27 (31.4%)	26 (27.7%)	53 (29.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-item-mpnsaf-gba-improv.sas V.03.05 Output file: t-gba-improv-MPN0103.pdf 29AUG2023: 9:42

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Table 2.6104: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #4 at Week 24

Double-blind Phase

ITT-Anemic Analysis Set

	MMB (N = 86)	RUX (N = 94)	Total (N = 180)
MPN0104 - Inactivity at Week 24			
Responder, n(%)	13 (15.1%)	23 (24.5%)	36 (20.0%)
Unadjusted Inverse Relative Risk (95% CI)	1.62 (0.88, 2.99)		
p-value [1]	0.12		
Unadjusted Inverse Odds Ratio (95% CI)	1.82 (0.86, 3.87)		
p-value [1]	0.12		
Unadjusted Absolute Risk Difference (95% CI)	-0.09 (-0.21, 0.02)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.59 (0.86, 2.92)		
p-value [2]	0.14		
Non-Responder, n(%)	73 (84.9%)	71 (75.5%)	144 (80.0%)
Non-missing	46 (53.5%)	45 (47.9%)	91 (50.6%)
Missing	27 (31.4%)	26 (27.7%)	53 (29.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

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Table 2.6105: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #5 at Week 24
Double-blind Phase
ITT-Anemic Analysis Set

	MMB (N = 86)	RUX (N = 94)	Total (N = 180)
MPN0105 - Headaches at Week 24			
Responder, n(%)	14 (16.3%)	13 (13.8%)	27 (15.0%)
Unadjusted Inverse Relative Risk (95% CI)	0.85 (0.42, 1.70)		
p-value [1]	0.65		
Unadjusted Inverse Odds Ratio (95% CI)	0.83 (0.36, 1.87)		
p-value [1]	0.65		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.08, 0.13)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Non-Responder, n(%)	72 (83.7%)	81 (86.2%)	153 (85.0%)
Non-missing	45 (52.3%)	55 (58.5%)	100 (55.6%)
Missing	27 (31.4%)	26 (27.7%)	53 (29.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-item-mpnsaf-gba-improv.sas V.03.05 Output file: t-gba-improv-MPN0105.pdf 29AUG2023: 9:42

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Table 2.6106: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #6 at Week 24

Double-blind Phase

ITT-Anemic Analysis Set

	MMB (N = 86)	RUX (N = 94)	Total (N = 180)
MPN0106 - Concentration at Week 24			
Responder, n(%)	**14 (16.3%)**	**22 (23.4%)**	**36 (20.0%)**
Unadjusted Inverse Relative Risk (95% CI)	**1.44 (0.79, 2.63)**		
p-value [1]	**0.24**		
Unadjusted Inverse Odds Ratio (95% CI)	**1.57 (0.75, 3.31)**		
p-value [1]	**0.23**		
Unadjusted Absolute Risk Difference (95% CI)	**-0.07 (-0.19, 0.04)**		
Adjusted Inverse Relative Risk (95% CI) [2]	**NE**		
p-value [2]	**NE**		
Non-Responder, n(%)	**72 (83.7%)**	**72 (76.6%)**	**144 (80.0%)**
Non-missing	**45 (52.3%)**	**46 (48.9%)**	**91 (50.6%)**
Missing	**27 (31.4%)**	**26 (27.7%)**	**53 (29.4%)**

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

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Table 2.6107: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #7 at Week 24
Double-blind Phase
ITT-Anemic Analysis Set

	MMB (N = 86)	RUX (N = 94)	Total (N = 180)
MPN0107 - Dizziness at Week 24			
Responder, n(%)	19 (22.1%)	16 (17.0%)	35 (19.4%)
Unadjusted Inverse Relative Risk (95% CI)	0.77 (0.42, 1.40)		
p-value [1]	0.39		
Unadjusted Inverse Odds Ratio (95% CI)	0.72 (0.34, 1.52)		
p-value [1]	0.39		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.07, 0.17)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.82 (0.45, 1.47)		
p-value [2]	0.50		
Non-Responder, n(%)	67 (77.9%)	78 (83.0%)	145 (80.6%)
Non-missing	40 (46.5%)	52 (55.3%)	92 (51.1%)
Missing	27 (31.4%)	26 (27.7%)	53 (29.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-item-mpnsaf-gba-improv.sas V.03.05 Output file: t-gba-improv-MPN0107.pdf 29AUG2023: 9:42

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Table 2.6108: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #8 at Week 24

Double-blind Phase

ITT-Anemic Analysis Set

	MMB (N = 86)	RUX (N = 94)	Total (N = 180)
MPN0108 - Numbness at Week 24			
Responder, n(%)	17 (19.8%)	16 (17.0%)	33 (18.3%)
Unadjusted Inverse Relative Risk (95% CI)	0.86 (0.46, 1.60)		
p-value [1]	0.63		
Unadjusted Inverse Odds Ratio (95% CI)	0.83 (0.39, 1.77)		
p-value [1]	0.63		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.09, 0.14)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Non-Responder, n(%)	69 (80.2%)	78 (83.0%)	147 (81.7%)
Non-missing	42 (48.8%)	52 (55.3%)	94 (52.2%)
Missing	27 (31.4%)	26 (27.7%)	53 (29.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

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Table 2.6109: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #9 at Week 24

Double-blind Phase

ITT-Anemic Analysis Set

	MMB (N = 86)	RUX (N = 94)	Total (N = 180)
MPN0109 - Difficulty Sleeping at Week 24			
Responder, n(%)	24 (27.9%)	29 (30.9%)	53 (29.4%)
Unadjusted Inverse Relative Risk (95% CI)	1.11 (0.70, 1.74)		
p-value [1]	0.67		
Unadjusted Inverse Odds Ratio (95% CI)	1.15 (0.61, 2.19)		
p-value [1]	0.67		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.16, 0.10)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.14 (0.73, 1.79)		
p-value [2]	0.57		
Non-Responder, n(%)	62 (72.1%)	65 (69.1%)	127 (70.6%)
Non-missing	35 (40.7%)	39 (41.5%)	74 (41.1%)
Missing	27 (31.4%)	26 (27.7%)	53 (29.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

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Table 2.6110: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #10 at Week 24

Double-blind Phase

ITT-Anemic Analysis Set

	MMB (N = 86)	RUX (N = 94)	Total (N = 180)
MPN0110 - Depression at Week 24			
Responder, n(%)	13 (15.1%)	18 (19.1%)	31 (17.2%)
Unadjusted Inverse Relative Risk (95% CI)	1.27 (0.66, 2.43)		
p-value [1]	0.48		
Unadjusted Inverse Odds Ratio (95% CI)	1.33 (0.61, 2.91)		
p-value [1]	0.48		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.15, 0.07)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Non-Responder, n(%)	73 (84.9%)	76 (80.9%)	149 (82.8%)
Non-missing	46 (53.5%)	50 (53.2%)	96 (53.3%)
Missing	27 (31.4%)	26 (27.7%)	53 (29.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

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Table 2.6111: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #11 at Week 24

Double-blind Phase

ITT-Anemic Analysis Set

	MMB (N = 86)	RUX (N = 94)	Total (N = 180)
MPN0111 - Sexual at Week 24			
Responder, n(%)	12 (14.0%)	11 (11.7%)	23 (12.8%)
Unadjusted Inverse Relative Risk (95% CI)	0.84 (0.39, 1.80)		
p-value [1]	0.65		
Unadjusted Inverse Odds Ratio (95% CI)	0.82 (0.34, 1.96)		
p-value [1]	0.65		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.08, 0.12)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.84 (0.39, 1.83)		
p-value [2]	0.67		
Non-Responder, n(%)	74 (86.0%)	83 (88.3%)	157 (87.2%)
Non-missing	47 (54.7%)	57 (60.6%)	104 (57.8%)
Missing	27 (31.4%)	26 (27.7%)	53 (29.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

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Table 2.6112: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #12 at Week 24

Double-blind Phase

ITT-Anemic Analysis Set

	MMB (N = 86)	RUX (N = 94)	Total (N = 180)
MPN0112 - Cough at Week 24			
Responder, n(%)	10 (11.6%)	19 (20.2%)	29 (16.1%)
Unadjusted Inverse Relative Risk (95% CI)	1.74 (0.86, 3.53)		
p-value [1]	0.13		
Unadjusted Inverse Odds Ratio (95% CI)	1.93 (0.84, 4.41)		
p-value [1]	0.12		
Unadjusted Absolute Risk Difference (95% CI)	-0.09 (-0.19, 0.02)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.68 (0.85, 3.33)		
p-value [2]	0.14		
Non-Responder, n(%)	76 (88.4%)	75 (79.8%)	151 (83.9%)
Non-missing	49 (57.0%)	49 (52.1%)	98 (54.4%)
Missing	27 (31.4%)	26 (27.7%)	53 (29.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

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Table 2.6113: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #13 at Week 24

Double-blind Phase

ITT-Anemic Analysis Set

	MMB (N = 86)	RUX (N = 94)	Total (N = 180)
MPN0113 - Night Sweats at Week 24			
Responder, n(%)	**27 (31.4%)**	**33 (35.1%)**	**60 (33.3%)**
Unadjusted Inverse Relative Risk (95% CI)	**1.12 (0.74, 1.70)**		
p-value [1]	**0.60**		
Unadjusted Inverse Odds Ratio (95% CI)	**1.18 (0.63, 2.20)**		
p-value [1]	**0.60**		
Unadjusted Absolute Risk Difference (95% CI)	**-0.04 (-0.17, 0.10)**		
Adjusted Inverse Relative Risk (95% CI) [2]	**1.09 (0.72, 1.64)**		
p-value [2]	**0.68**		
Non-Responder, n(%)	**59 (68.6%)**	**61 (64.9%)**	**120 (66.7%)**
Non-missing	**32 (37.2%)**	**35 (37.2%)**	**67 (37.2%)**
Missing	**27 (31.4%)**	**26 (27.7%)**	**53 (29.4%)**

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

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Table 2.6114: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #14 at Week 24

Double-blind Phase

ITT-Anemic Analysis Set

	MMB (N = 86)	RUX (N = 94)	Total (N = 180)
MPN0114 - Itching at Week 24			
Responder, n(%)	15 (17.4%)	17 (18.1%)	32 (17.8%)
Unadjusted Inverse Relative Risk (95% CI)	1.04 (0.55, 1.95)		
p-value [1]	0.91		
Unadjusted Inverse Odds Ratio (95% CI)	1.05 (0.49, 2.25)		
p-value [1]	0.91		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.12, 0.11)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Non-Responder, n(%)	71 (82.6%)	77 (81.9%)	148 (82.2%)
Non-missing	44 (51.2%)	51 (54.3%)	95 (52.8%)
Missing	27 (31.4%)	26 (27.7%)	53 (29.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

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Table 2.6115: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #15 at Week 24

Double-blind Phase

ITT-Anemic Analysis Set

	MMB (N = 86)	RUX (N = 94)	Total (N = 180)
MPN0115 - Bone Pain at Week 24			
Responder, n(%)	21 (24.4%)	18 (19.1%)	39 (21.7%)
Unadjusted Inverse Relative Risk (95% CI)	0.78 (0.45, 1.37)		
p-value [1]	0.39		
Unadjusted Inverse Odds Ratio (95% CI)	0.73 (0.36, 1.49)		
p-value [1]	0.39		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.07, 0.17)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.85 (0.49, 1.46)		
p-value [2]	0.56		
Non-Responder, n(%)	65 (75.6%)	76 (80.9%)	141 (78.3%)
Non-missing	38 (44.2%)	50 (53.2%)	88 (48.9%)
Missing	27 (31.4%)	26 (27.7%)	53 (29.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

GSK Oncology

Study GS-US-352-0101

Table 2.6116: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #16 at Week 24

Double-blind Phase

ITT-Anemic Analysis Set

	MMB (N = 86)	RUX (N = 94)	Total (N = 180)
MPN0116 - Fever at Week 24			
Responder, n(%)	4 (4.7%)	6 (6.4%)	10 (5.6%)
Unadjusted Inverse Relative Risk (95% CI)	1.37 (0.40, 4.70)		
p-value [1]	0.61		
Unadjusted Inverse Odds Ratio (95% CI)	1.40 (0.38, 5.13)		
p-value [1]	0.61		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.08, 0.05)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Non-Responder, n(%)	82 (95.3%)	88 (93.6%)	170 (94.4%)
Non-missing	55 (64.0%)	62 (66.0%)	117 (65.0%)
Missing	27 (31.4%)	26 (27.7%)	53 (29.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

GSK Oncology

Study GS-US-352-0101

Table 2.6117: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #17 at Week 24

Double-blind Phase

ITT-Anemic Analysis Set

	MMB (N = 86)	RUX (N = 94)	Total (N = 180)
MPN0117 - Weight Loss in 6 Months at Week 24			
Responder, n(%)	28 (32.6%)	28 (29.8%)	56 (31.1%)
Unadjusted Inverse Relative Risk (95% CI)	0.91 (0.59, 1.41)		
p-value [1]	0.69		
Unadjusted Inverse Odds Ratio (95% CI)	0.88 (0.47, 1.65)		
p-value [1]	0.69		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.11, 0.16)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.91 (0.59, 1.41)		
p-value [2]	0.69		
Non-Responder, n(%)	58 (67.4%)	66 (70.2%)	124 (68.9%)
Non-missing	31 (36.0%)	40 (42.6%)	71 (39.4%)
Missing	27 (31.4%)	26 (27.7%)	53 (29.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

GSK Oncology

Study GS-US-352-0101

Table 2.6118: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #18 at Week 24

Double-blind Phase

ITT-Anemic Analysis Set

	MMB (N = 86)	RUX (N = 94)	Total (N = 180)
MPN0118 - Overall Quality of Life at Week 24			
Responder, n(%)	15 (17.4%)	24 (25.5%)	39 (21.7%)
Unadjusted Inverse Relative Risk (95% CI)	1.46 (0.82, 2.60)		
p-value [1]	0.19		
Unadjusted Inverse Odds Ratio (95% CI)	1.62 (0.79, 3.35)		
p-value [1]	0.19		
Unadjusted Absolute Risk Difference (95% CI)	-0.08 (-0.20, 0.04)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.49 (0.84, 2.62)		
p-value [2]	0.17		
Non-Responder, n(%)	71 (82.6%)	70 (74.5%)	141 (78.3%)
Non-missing	44 (51.2%)	44 (46.8%)	88 (48.9%)
Missing	27 (31.4%)	26 (27.7%)	53 (29.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

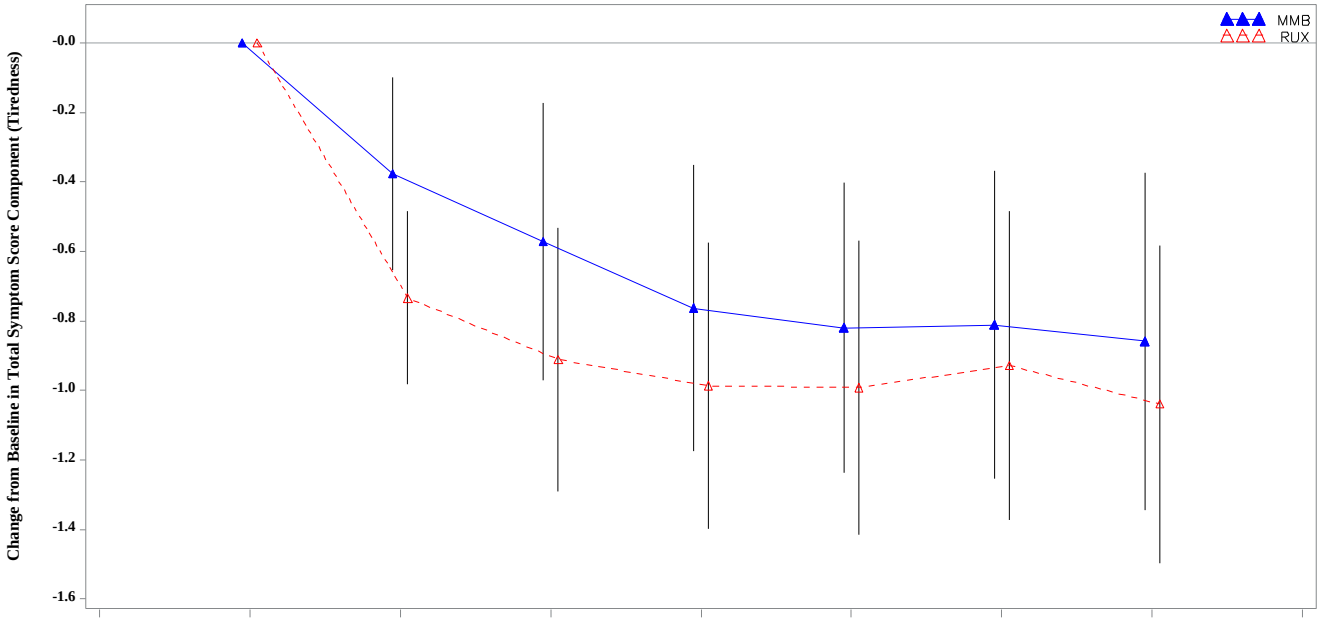
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

1.4.2 mMPN-SAF TSS

Figure 2.0801: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in TSS and Individual Item Scores (Every 4 Weeks) by Treatment
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MMPN02-Wrst Inc Pst 24H: Tiredness



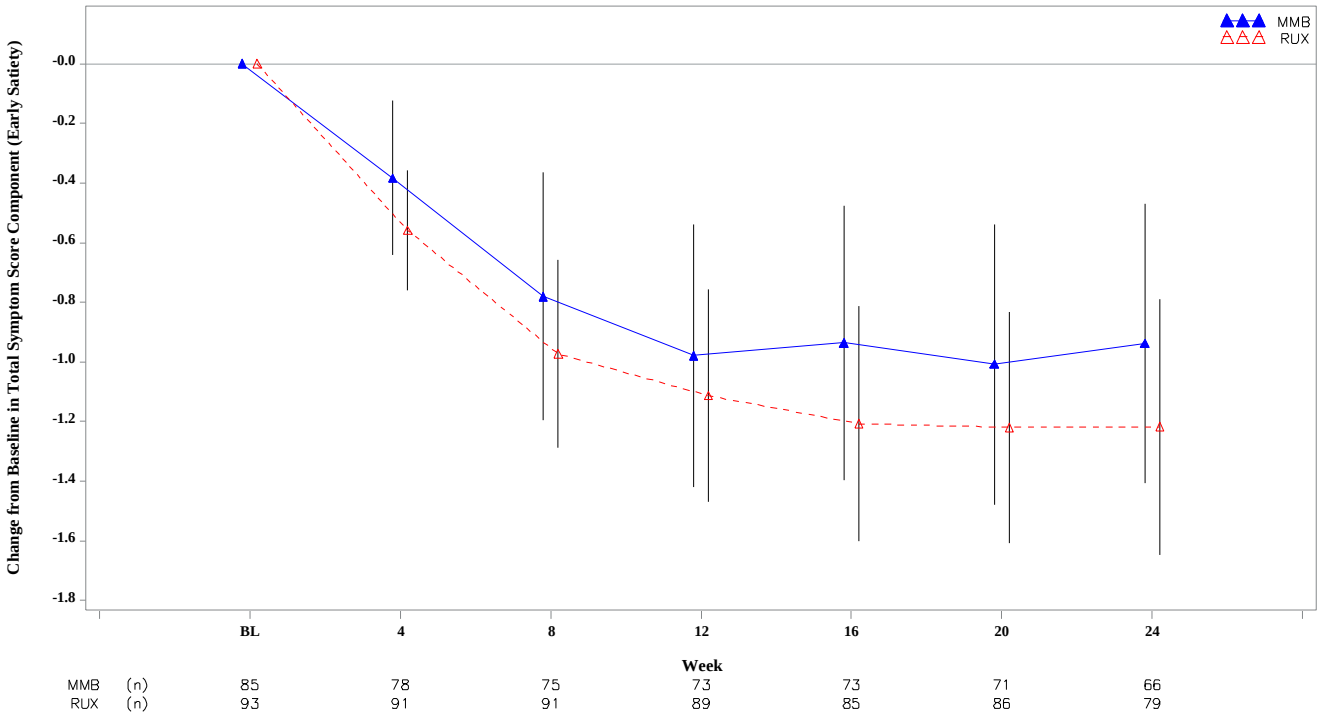
MMB	(n)	85	78	75	73	73	71	66
RUX	(n)	93	91	91	89	85	86	79

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
TSS = Total Symptom Score

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-line-chg-tss.pdf 30AUG2023:12:28

Figure 2.0801: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in TSS and Individual Item Scores (Every 4 Weeks) by Treatment
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MMPN02-Wrst Inc Pst 24H: Early Satiety



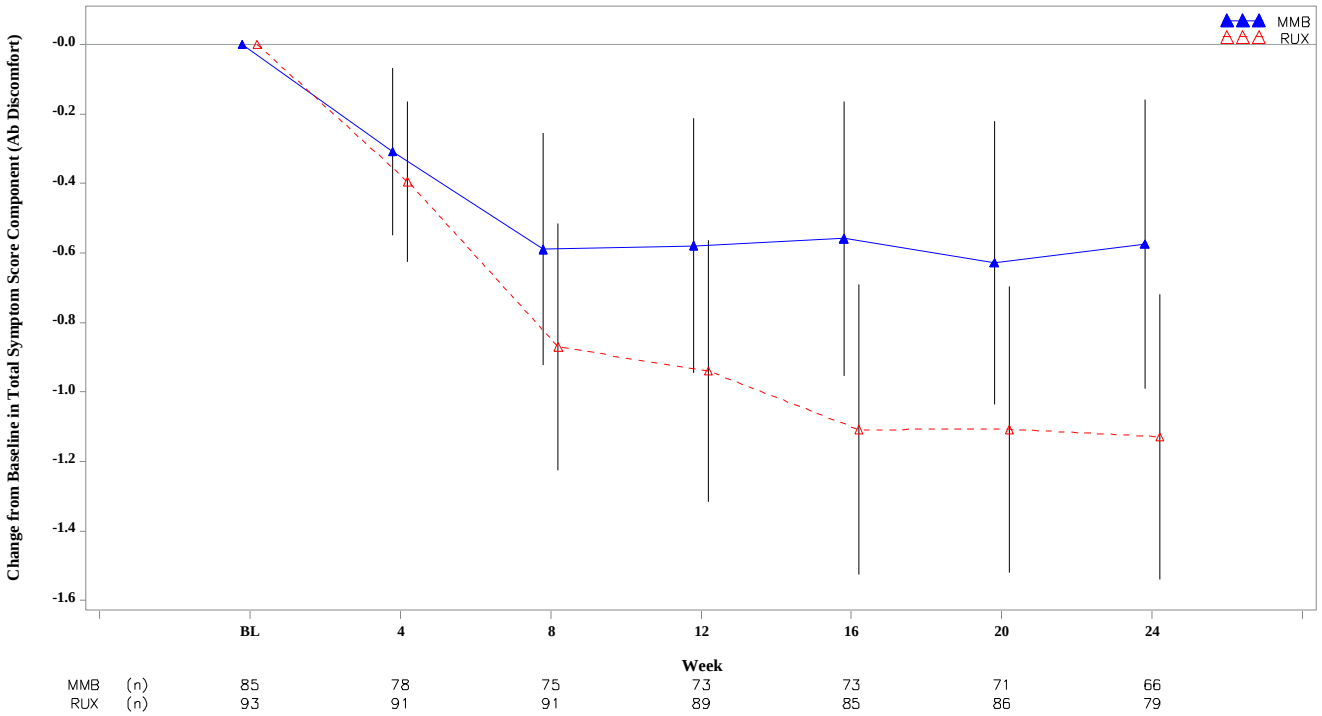
		BL	4	8	12	16	20	24
MMB	(n)	85	78	75	73	73	71	66
RUX	(n)	93	91	91	89	85	86	79

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
TSS = Total Symptom Score

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-line-chg-tss.pdf 30AUG2023:12:28

Figure 2.0801: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in TSS and Individual Item Scores (Every 4 Weeks) by Treatment
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MMPN02-Wrst Inc Pst 24H: Ab Discomfort



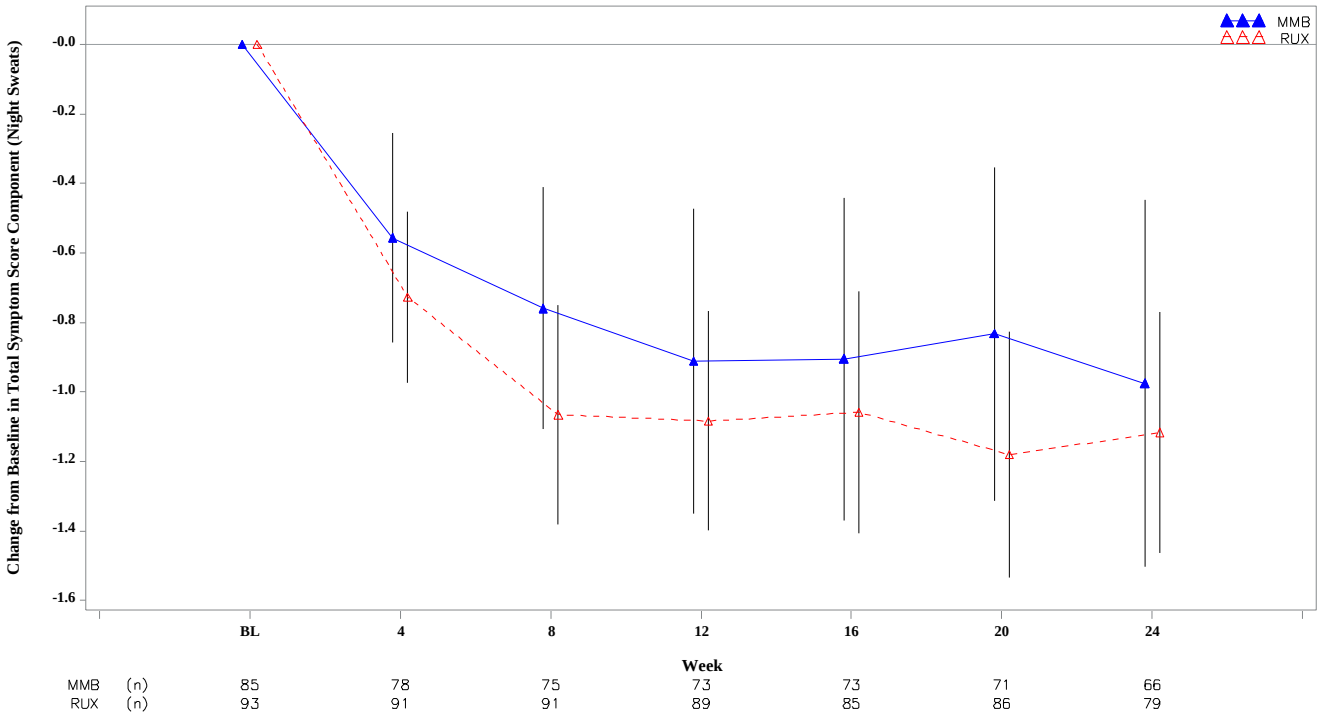
MMB	(n)	85	78	75	73	73	71	66
RUX	(n)	93	91	91	89	85	86	79

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
TSS = Total Symptom Score

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-line-chg-tss.pdf 30AUG2023:12:28

Figure 2.0801: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in TSS and Individual Item Scores (Every 4 Weeks) by Treatment
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MMPN02-Wrst Inc Pst 24H: Night Sweats



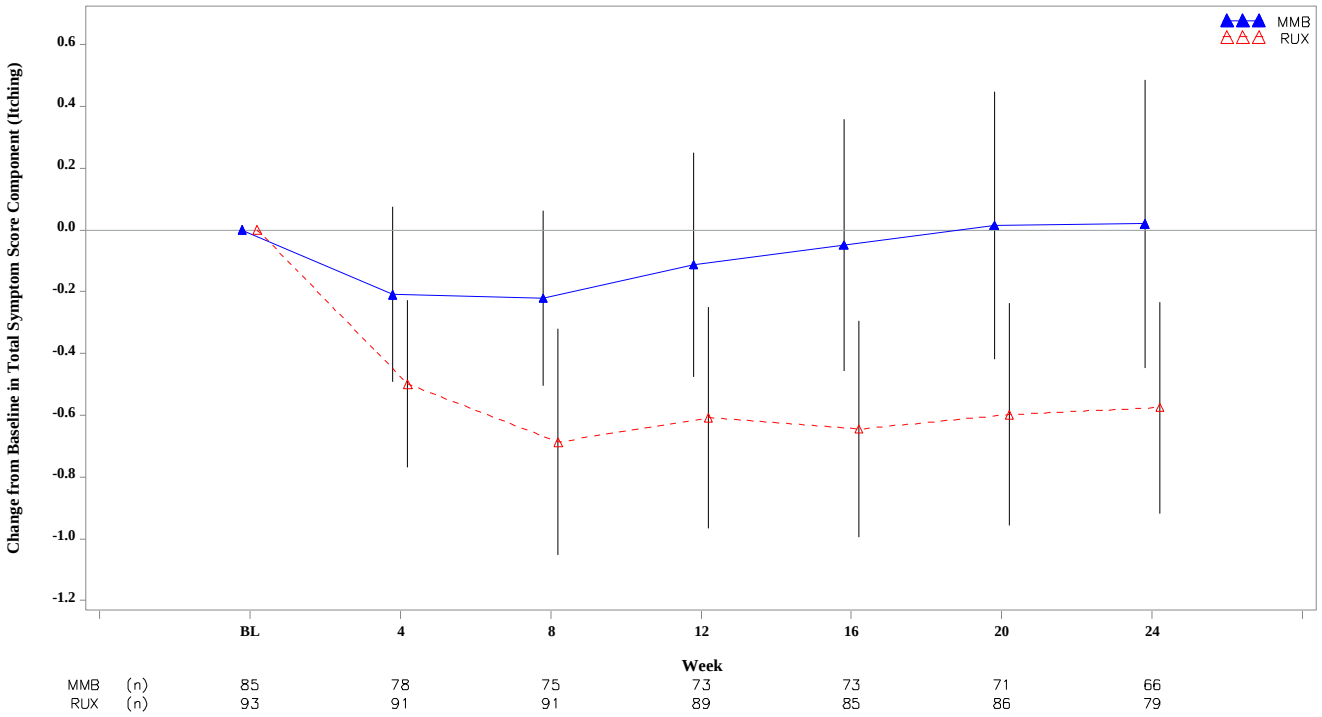
MMB	(n)	85	78	75	73	73	71	66
RUX	(n)	93	91	91	89	85	86	79

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
TSS = Total Symptom Score

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-line-chg-tss.pdf 30AUG2023:12:28

Figure 2.0801: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in TSS and Individual Item Scores (Every 4 Weeks) by Treatment
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MMPN02-Wrst Inc Pst 24H: Itching



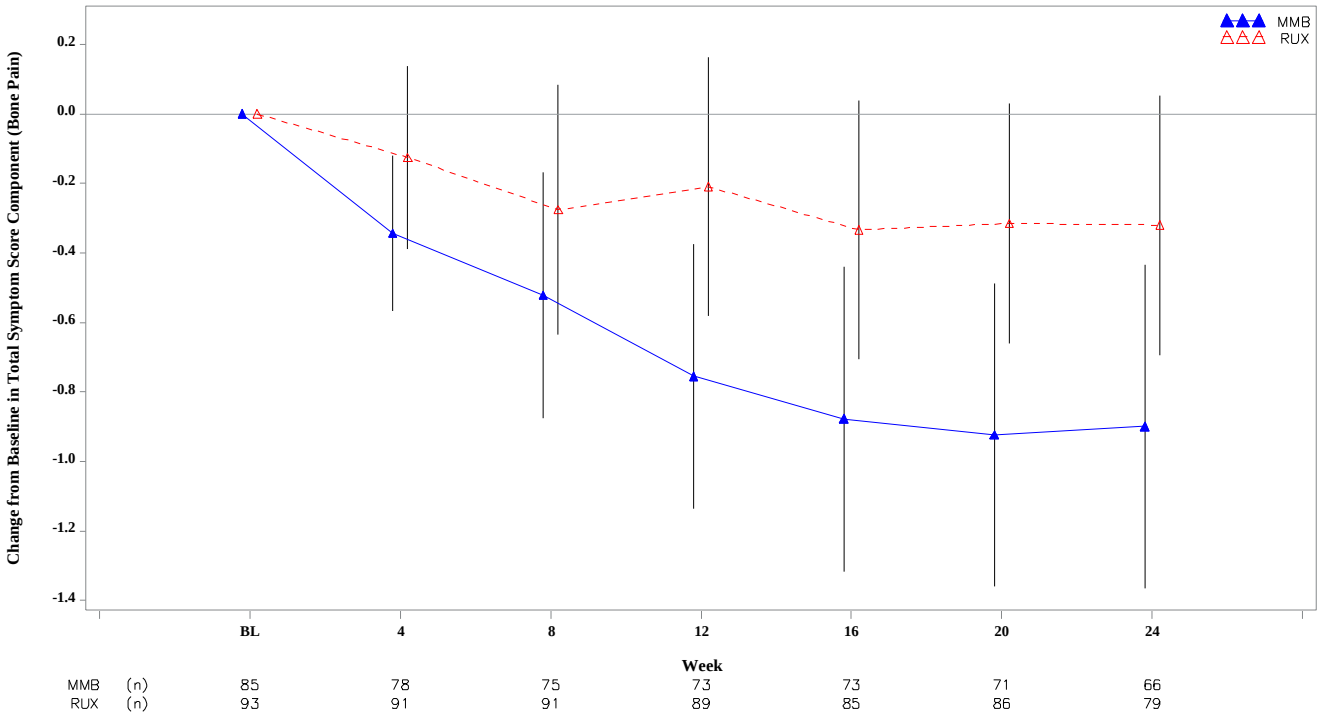
		BL	4	8	12	16	20	24
MMB	(n)	85	78	75	73	73	71	66
RUX	(n)	93	91	91	89	85	86	79

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
TSS = Total Symptom Score

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-line-chg-tss.pdf 30AUG2023:12:29

Figure 2.0801: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in TSS and Individual Item Scores (Every 4 Weeks) by Treatment
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MMPN02-Wrst Inc Pst 24H: Bone Pain



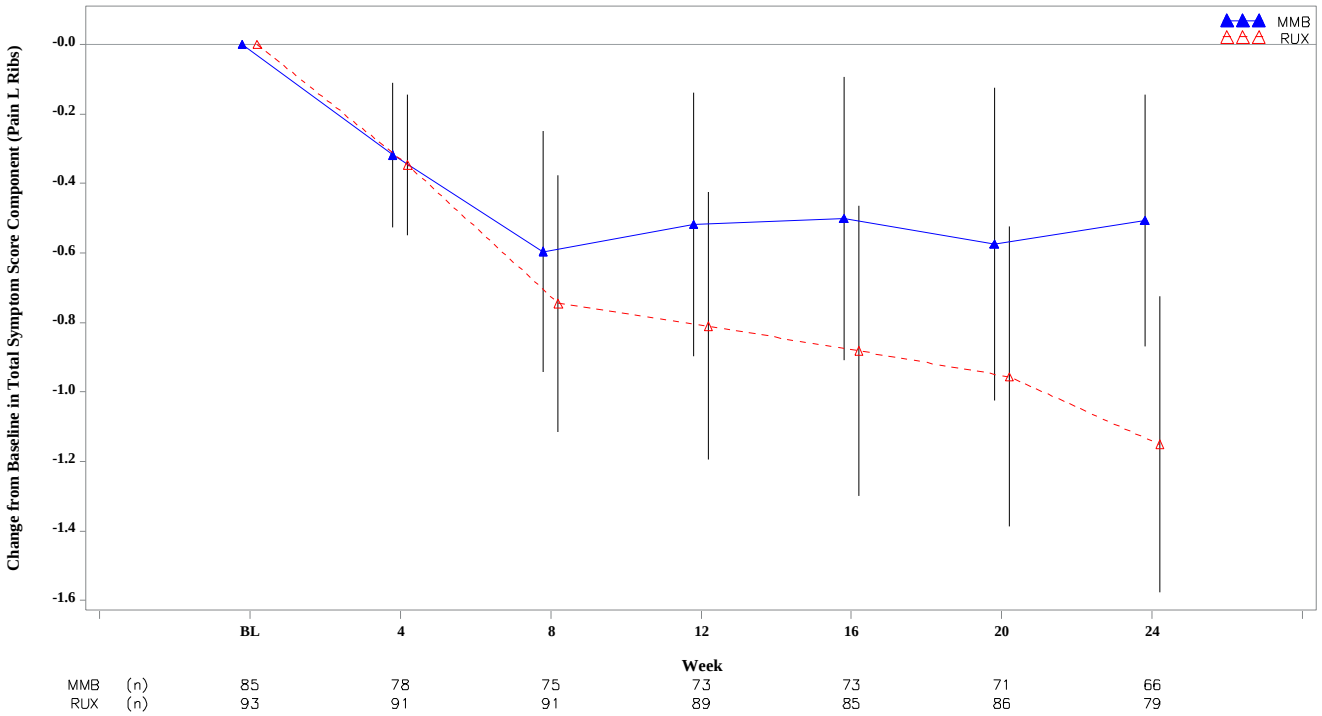
MMB	(n)	85	78	75	73	73	71	66
RUX	(n)	93	91	91	89	85	86	79

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
TSS = Total Symptom Score

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-line-chg-tss.pdf 30AUG2023:12:29

Figure 2.0801: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in TSS and Individual Item Scores (Every 4 Weeks) by Treatment
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MMPN02-Wrst Inc Pst 24H: Pain L Ribs



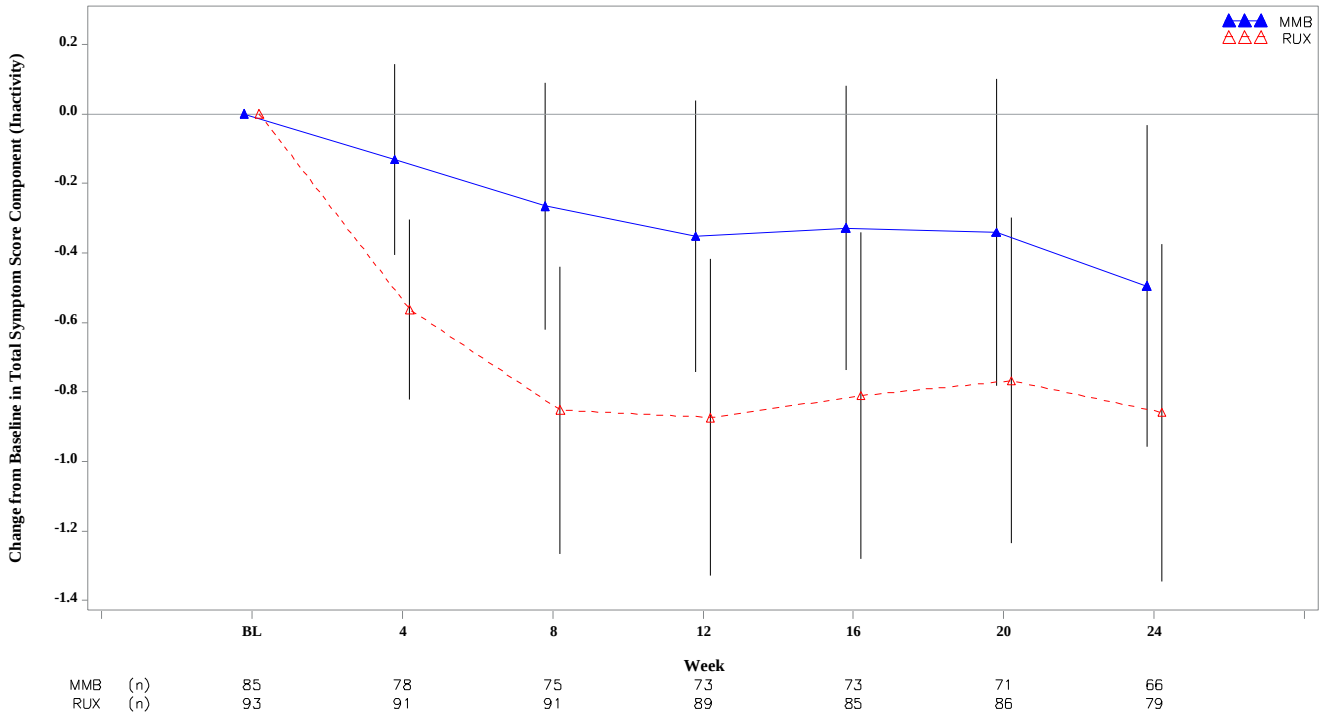
MMB	(n)	85	78	75	73	73	71	66
RUX	(n)	93	91	91	89	85	86	79

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
TSS = Total Symptom Score

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-line-chg-tss.pdf 30AUG2023:12:29

Figure 2.0801: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in TSS and Individual Item Scores (Every 4 Weeks) by Treatment
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MMPN02-Wrst Inc Pst 24H: Inactivity



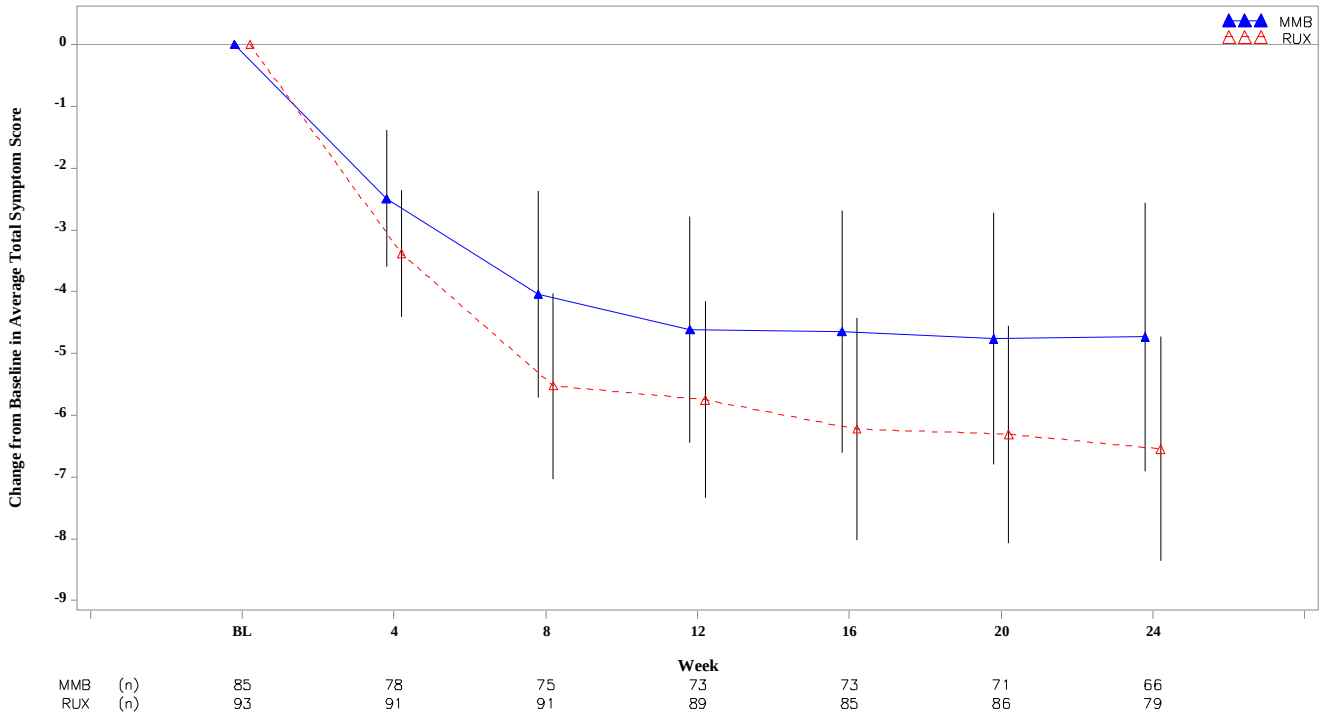
		BL	4	8	12	16	20	24
MMB	(n)	85	78	75	73	73	71	66
RUX	(n)	93	91	91	89	85	86	79

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
TSS = Total Symptom Score

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-line-chg-tss.pdf 30AUG2023:12:29

Figure 2.0801: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in TSS and Individual Item Scores (Every 4 Weeks) by Treatment
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=Average Daily Total Symtom Score



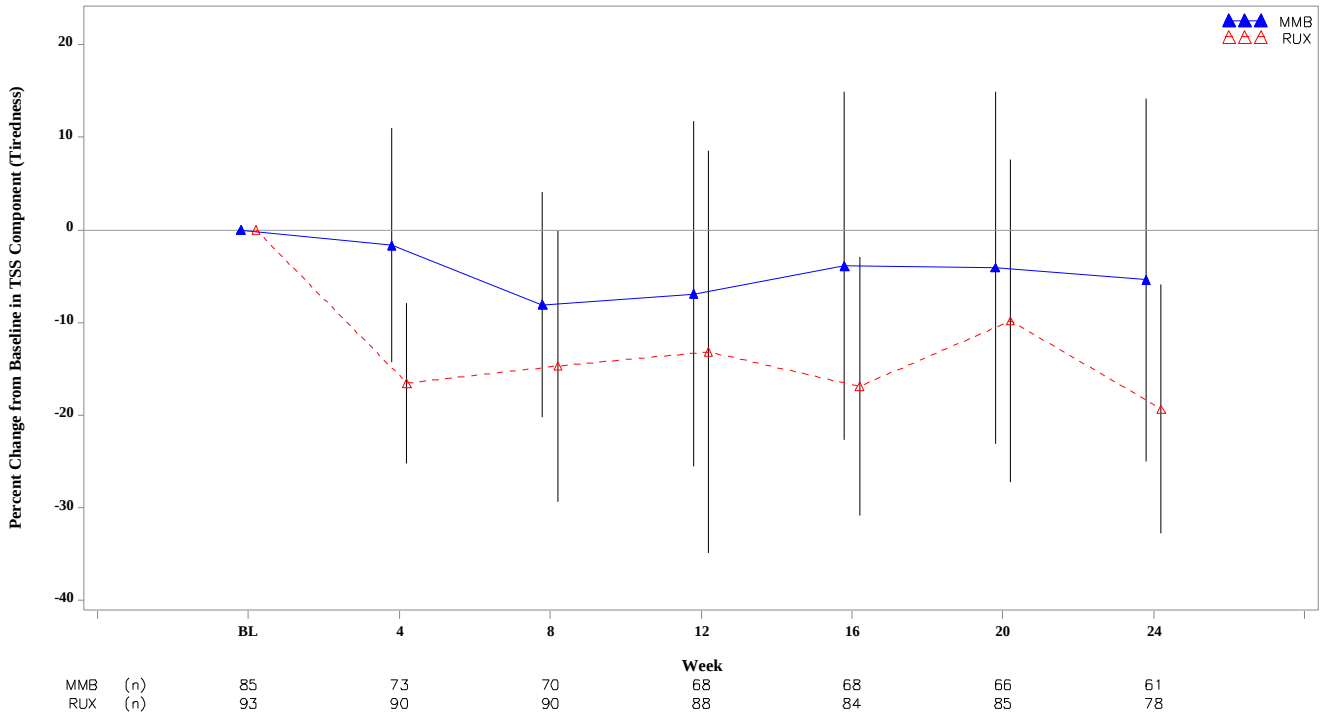
MMB	(n)	85	78	75	73	73	71	66
RUX	(n)	93	91	91	89	85	86	79

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
TSS = Total Symptom Score

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-line-chg-tss.pdf 30AUG2023:12:29

Figure 2.0802: Mean (incl. 95% CI) Plot of % Change from Baseline (including Baseline) in TSS and Individual Item Scores (Every 4 Weeks) by Treatment
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MMPN02-Wrst Inc Pst 24H: Tiredness



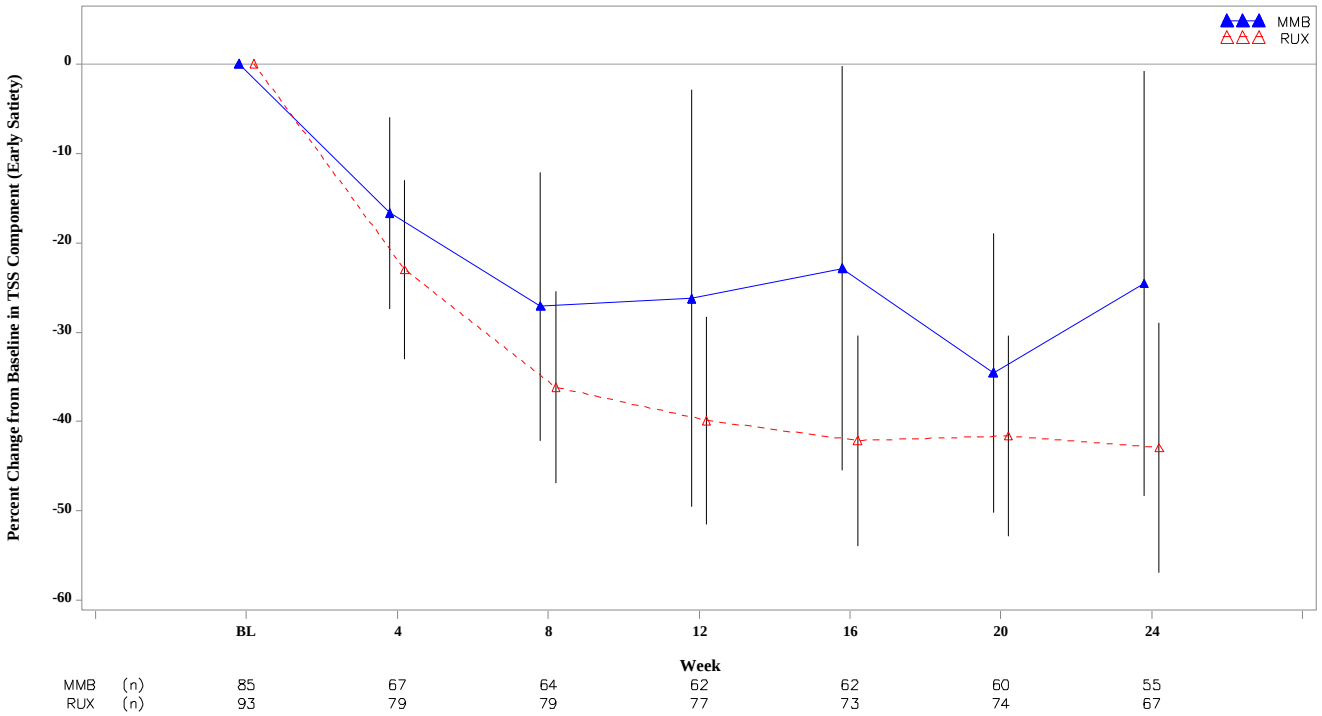
MMB	(n)	85	73	70	68	68	66	61
RUX	(n)	93	90	90	88	84	85	78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
TSS = Total Symptom Score

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-line-pchg-tss.pdf 30AUG2023:12:29

Figure 2.0802: Mean (incl. 95% CI) Plot of % Change from Baseline (including Baseline) in TSS and Individual Item Scores (Every 4 Weeks) by Treatment
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MMPN02-Wrst Inc Pst 24H: Early Satiety



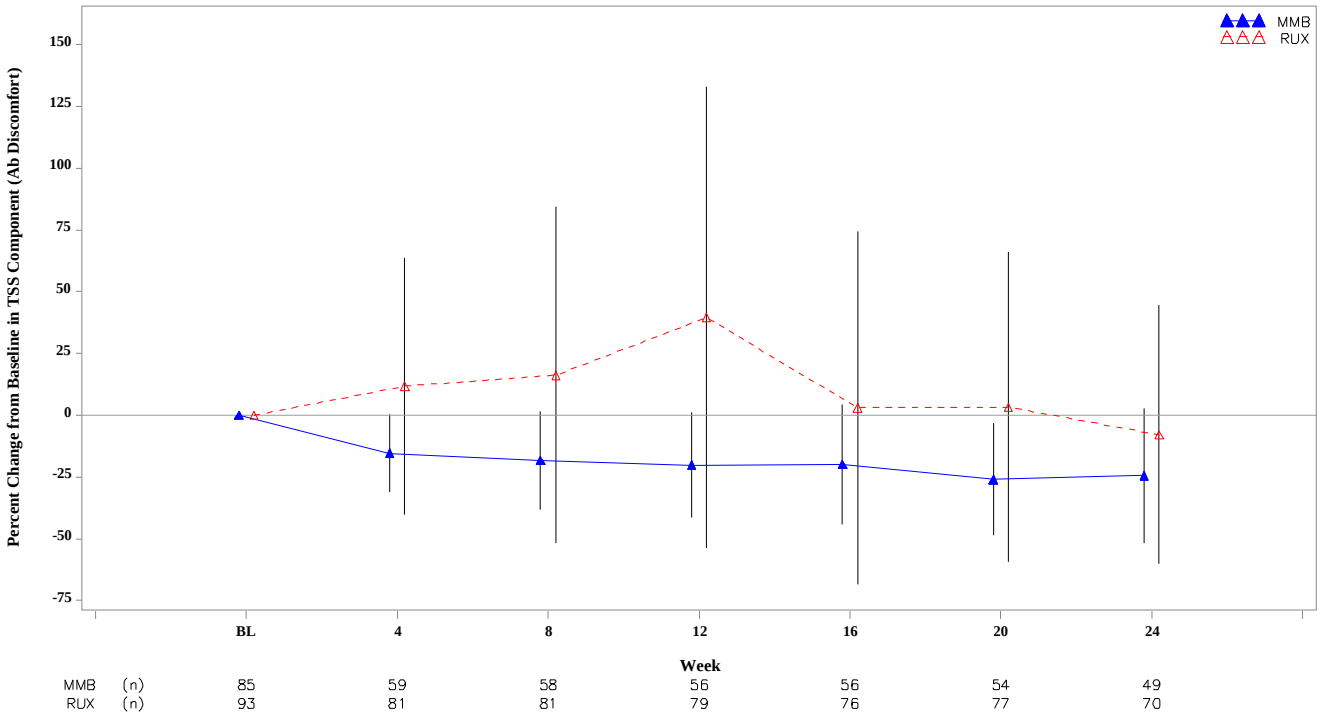
		BL	4	8	12	16	20	24
MMB	(n)	85	67	64	62	62	60	55
RUX	(n)	93	79	79	77	73	74	67

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
TSS = Total Symptom Score

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-line-pchg-tss.pdf 30AUG2023:12:29

Figure 2.0802: Mean (incl. 95% CI) Plot of % Change from Baseline (including Baseline) in TSS and Individual Item Scores (Every 4 Weeks) by Treatment
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MMPN02-Wrst Inc Pst 24H: Ab Discomfort



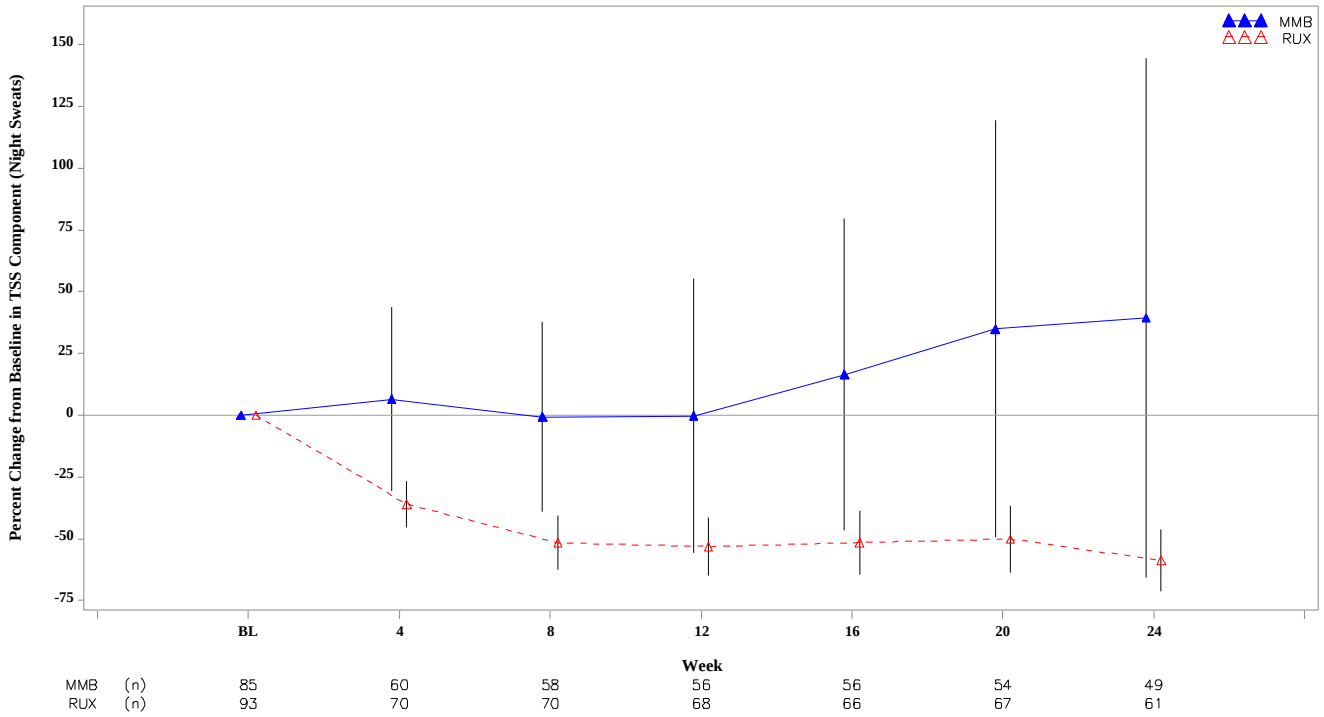
MMB	(n)	85	59	58	56	56	54	49
RUX	(n)	93	81	81	79	76	77	70

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
TSS = Total Symptom Score

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-line-pchg-tss.pdf 30AUG2023:12:29

Figure 2.0802: Mean (incl. 95% CI) Plot of % Change from Baseline (including Baseline) in TSS and Individual Item Scores (Every 4 Weeks) by Treatment
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MMPN02-Wrst Inc Pst 24H: Night Sweats



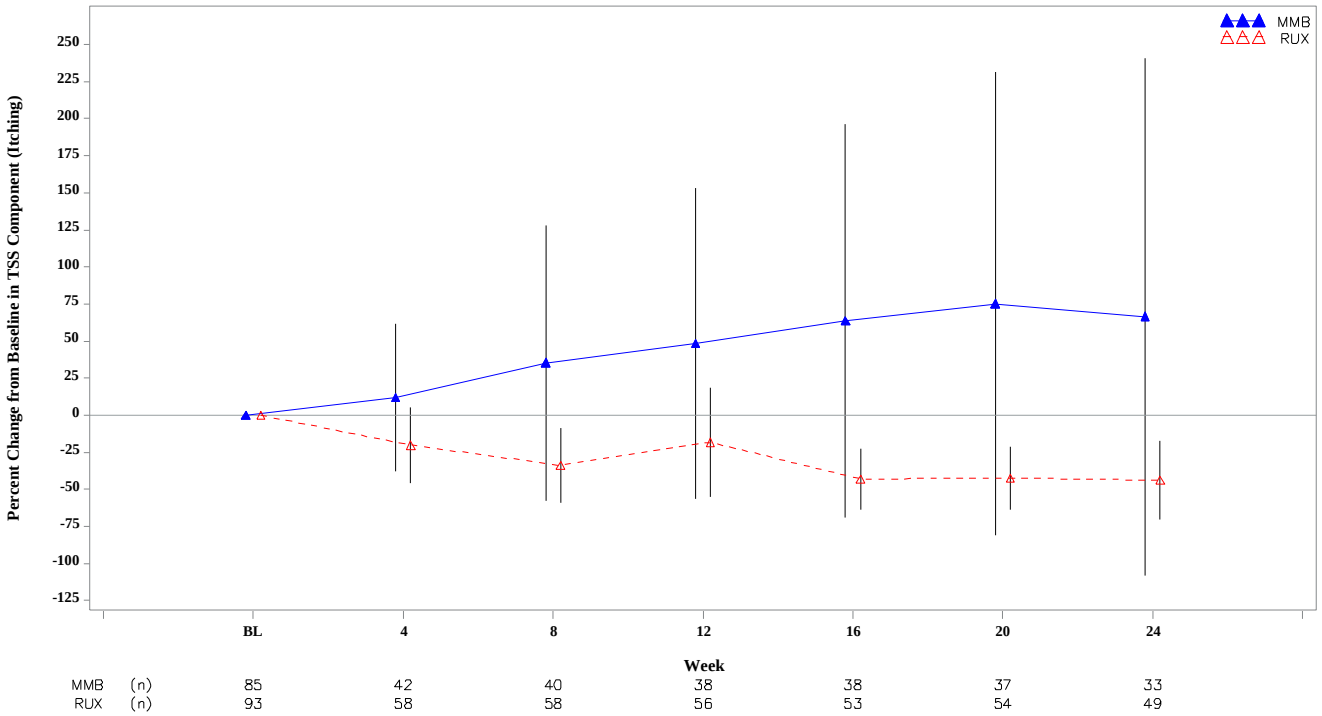
MMB	(n)	85	60	58	56	56	54	49
RUX	(n)	93	70	70	68	66	67	61

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
TSS = Total Symptom Score

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-line-pchg-tss.pdf 30AUG2023:12:29

Figure 2.0802: Mean (incl. 95% CI) Plot of % Change from Baseline (including Baseline) in TSS and Individual Item Scores (Every 4 Weeks) by Treatment
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MMPN02-Wrst Inc Pst 24H: Itching



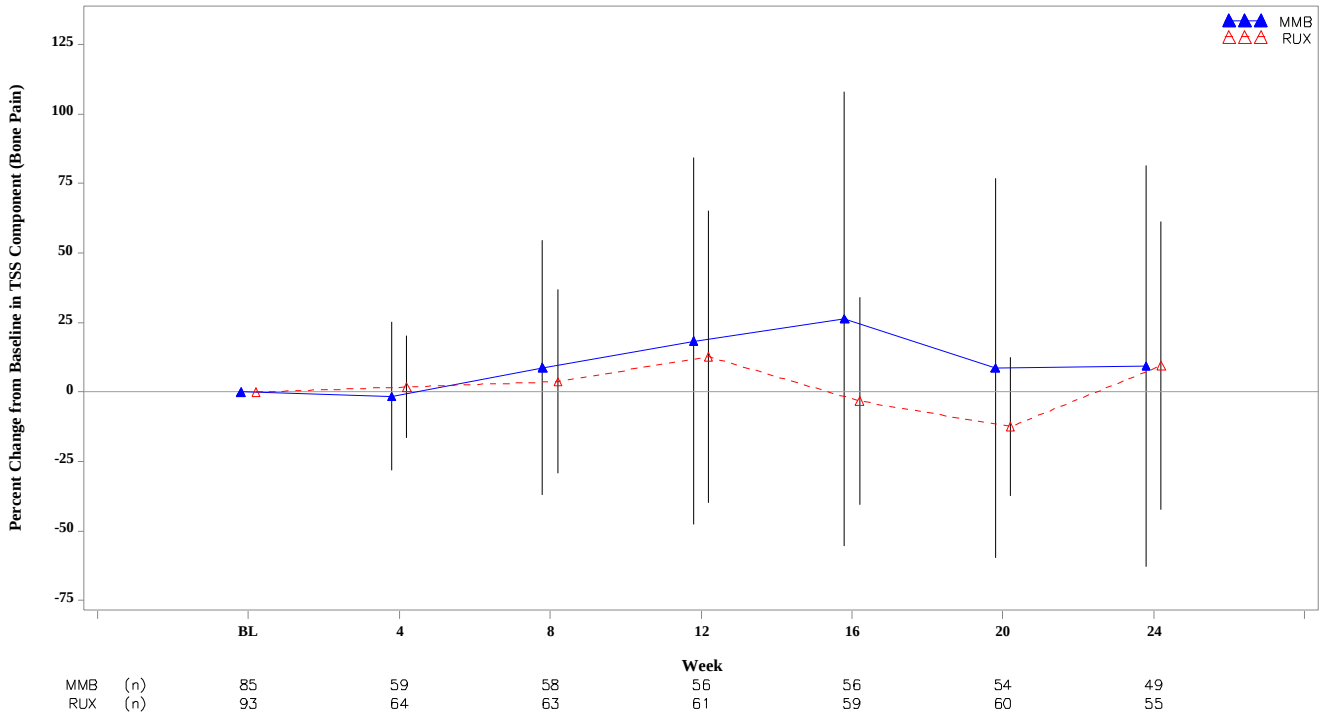
MMB	(n)	85	42	40	38	38	37	33
RUX	(n)	93	58	58	56	53	54	49

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
TSS = Total Symptom Score

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-line-pchg-tss.pdf 30AUG2023:12:29

Figure 2.0802: Mean (incl. 95% CI) Plot of % Change from Baseline (including Baseline) in TSS and Individual Item Scores (Every 4 Weeks) by Treatment
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MMPN02-Wrst Inc Pst 24H: Bone Pain



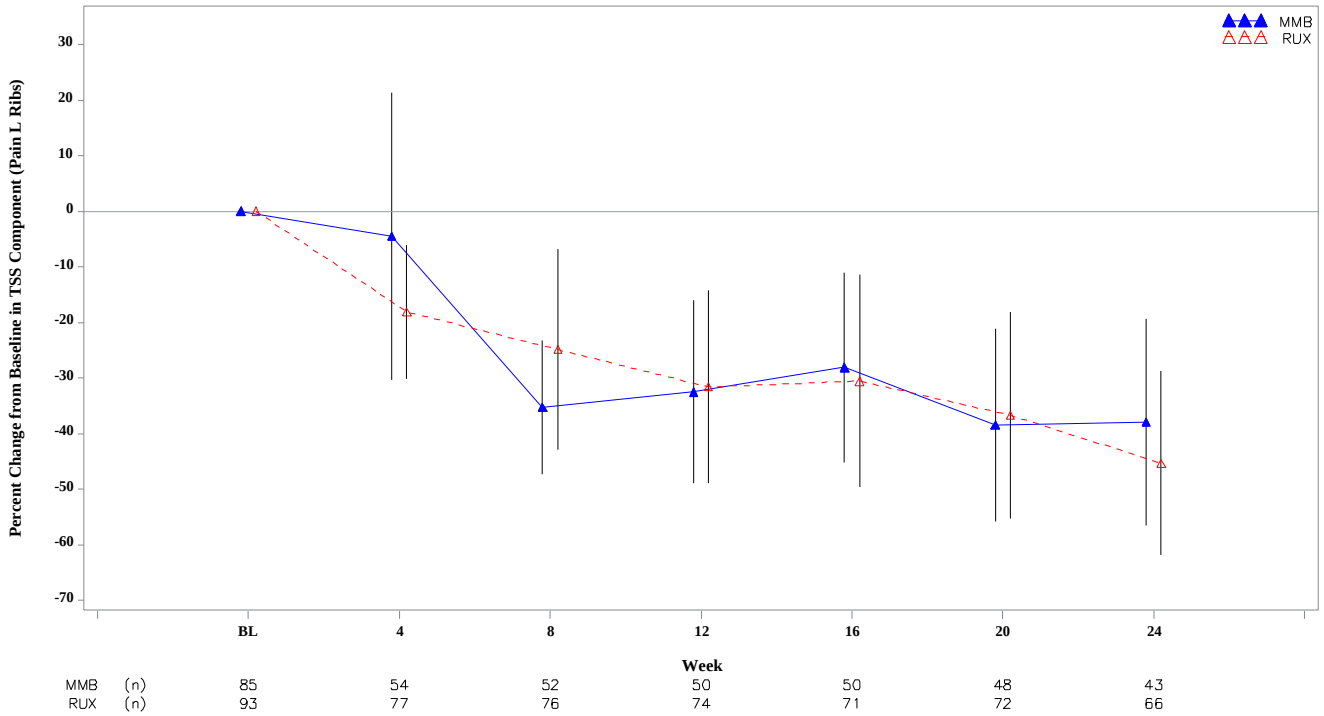
		BL	4	8	12	16	20	24
MMB	(n)	85	59	58	56	56	54	49
RUX	(n)	93	64	63	61	59	60	55

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
TSS = Total Symptom Score

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-line-pchg-tss.pdf 30AUG2023:12:29

Figure 2.0802: Mean (incl. 95% CI) Plot of % Change from Baseline (including Baseline) in TSS and Individual Item Scores (Every 4 Weeks) by Treatment
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MMPN02-Wrst Inc Pst 24H: Pain L Ribs



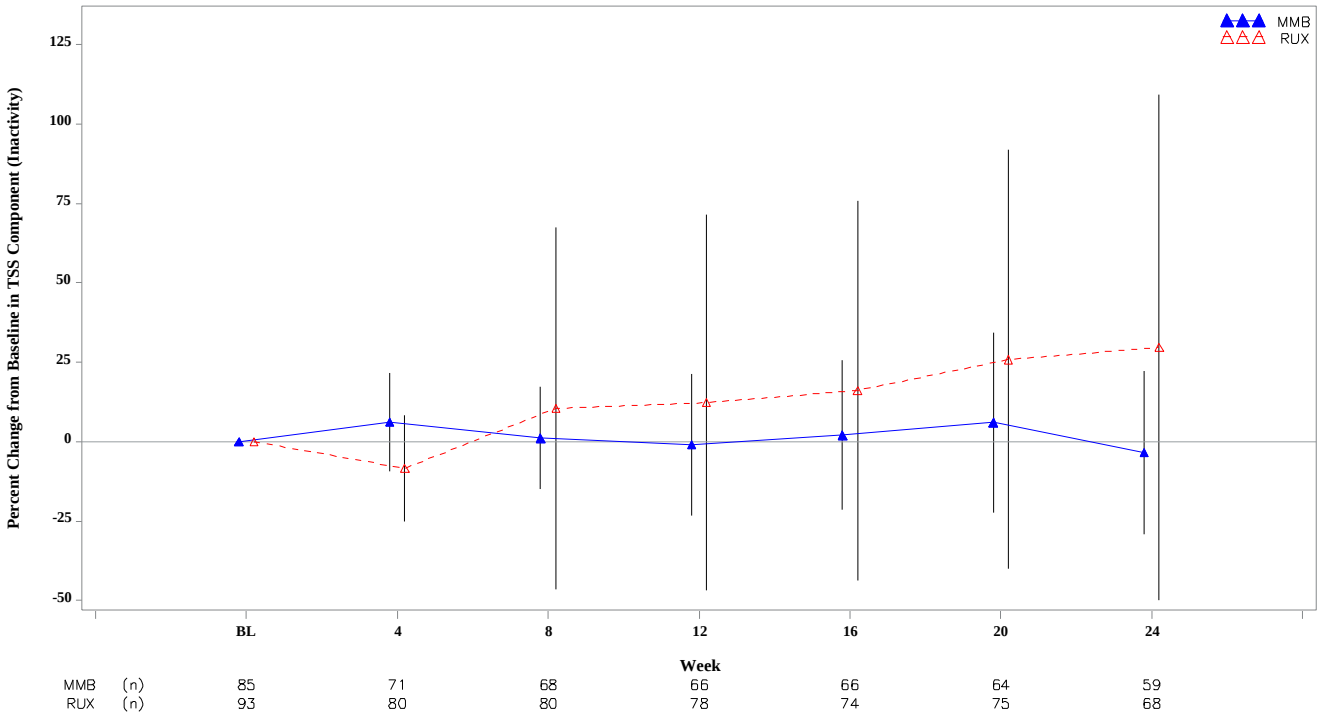
MMB	(n)	85	54	52	50	50	48	43
RUX	(n)	93	77	76	74	71	72	66

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
TSS = Total Symptom Score

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-line-pchg-tss.pdf 30AUG2023:12:29

Figure 2.0802: Mean (incl. 95% CI) Plot of % Change from Baseline (including Baseline) in TSS and Individual Item Scores (Every 4 Weeks) by Treatment
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=MMPN02-Wrst Inc Pst 24H: Inactivity



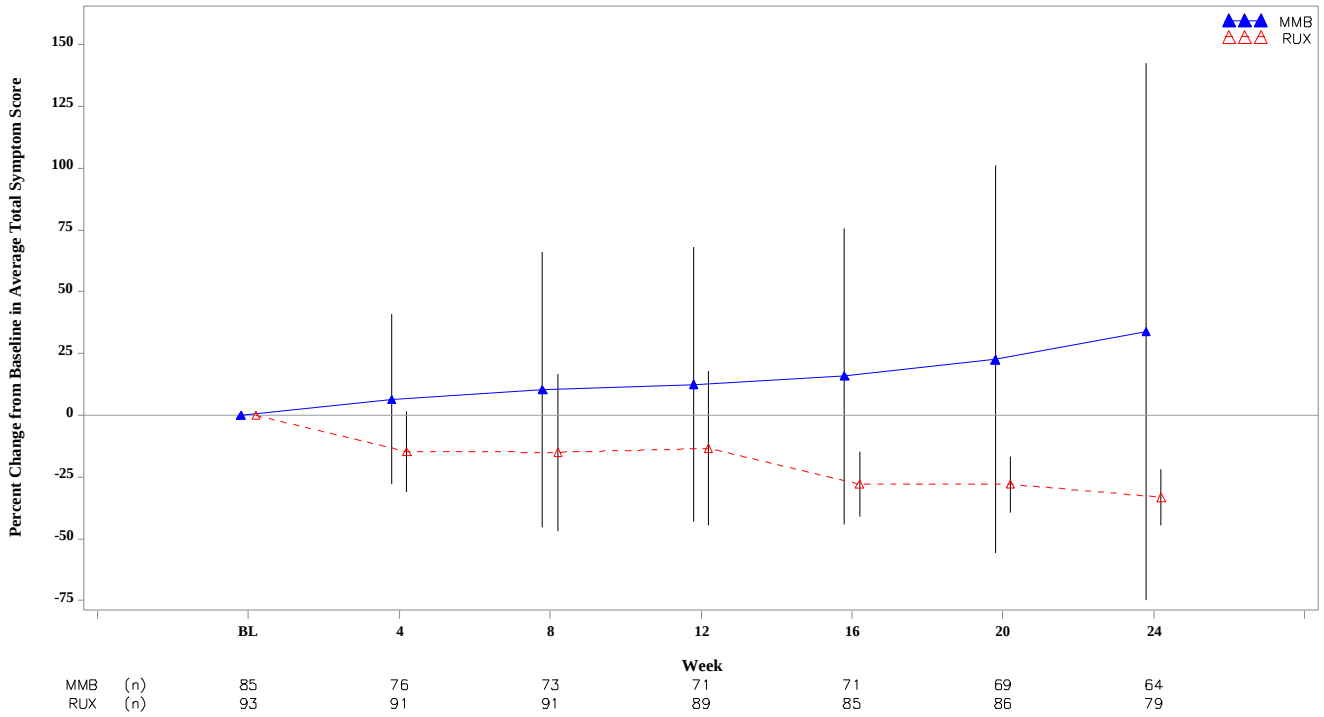
		BL	4	8	12	16	20	24
MMB	(n)	85	71	68	66	66	64	59
RUX	(n)	93	80	80	78	74	75	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
TSS = Total Symptom Score

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-line-pchg-tss.pdf 30AUG2023:12:29

Figure 2.0802: Mean (incl. 95% CI) Plot of % Change from Baseline (including Baseline) in TSS and Individual Item Scores (Every 4 Weeks) by Treatment
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=Average Daily Total Symtom Score



		BL	4	8	12	16	20	24
MMB	(n)	85	76	73	71	71	69	64
RUX	(n)	93	91	91	89	85	86	79

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
TSS = Total Symptom Score

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line.sas V.03.05 Output file: g-line-pchg-tss.pdf 30AUG2023:12:29

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
TSS Item: Tiredness		
Tiredness at Baseline		
n	85	93
Mean (SD)	4.5 (2.66)	4.1 (2.46)
Median	4.7	4.0
Q1, Q3	2.6, 6.9	2.1, 6.0
Min, Max	0.0, 9.9	0.0, 9.4
Tiredness at Week 4		
n	79	92
Mean (SD)	4.2 (2.55)	3.4 (2.24)
Median	3.8	3.4
Q1, Q3	2.1, 6.4	1.4, 5.0
Min, Max	0.0, 9.8	0.0, 9.0
Change in Tiredness at Week 4 from Baseline		
n	78	91
Mean (SD)	-0.4 (1.23)	-0.7 (1.20)
Median	-0.3	-0.6
Q1, Q3	-1.0, 0.4	-1.5, 0.0
Min, Max	-4.1, 2.8	-4.0, 3.8

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-tss-item-gba.sas V.03.05 Output file: t-chg-tss-item-gba.pdf 29AUG2023: 9:49

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Change from Baseline at Week 4		
n [1]	80	93
n [2]	78	91
MMRM: Least Squares Mean [SE] (95% CI)	-0.30 [0.14] (-0.59, -0.02)	-0.72 [0.14] (-0.98, -0.45)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.41 [0.18] (0.06, 0.76)	
MMRM: P-value	0.021	
Corrected Hedges' g (95% CI)	0.321 (0.017, 0.626)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.051	
Percent Change in Tiredness at Week 4 from Baseline		
n	73	90
Mean (SD)	-1.7 (54.19)	-16.5 (41.32)
Median	-9.7	-17.0
Q1, Q3	-26.1, 6.1	-34.3, -1.6
Min, Max	-87.5, 279.3	-100.0, 155.6
Difference in Percent Change from Baseline at Week 4		
n [1]	75	92
n [2]	73	90
MMRM: Least Squares Mean [SE] (95% CI)	-0.82 [6.10] (-12.87, 11.23)	-16.74 [5.55] (-27.71, -5.76)
MMRM: Least Squares Mean Difference [SE] (95% CI)	15.92 [7.56] (0.99, 30.84)	
MMRM: P-value	0.037	
Corrected Hedges' g (95% CI)	0.302 (-0.008, 0.613)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.075	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Tiredness at Week 8			
n	76	92	
Mean (SD)	3.9 (2.50)	3.2 (2.28)	
Median	3.4	2.9	
Q1, Q3	2.1, 5.5	1.4, 4.8	
Min, Max	0.0, 10.0	0.0, 9.6	
Change in Tiredness at Week 8 from Baseline			
n	75	91	
Mean (SD)	-0.6 (1.74)	-0.9 (1.82)	
Median	-0.5	-0.6	
Q1, Q3	-2.0, 0.4	-2.0, 0.2	
Min, Max	-4.0, 4.7	-6.1, 4.1	
Difference in Change from Baseline at Week 8			
n [1]	80	93	
n [2]	75	91	
MMRM: Least Squares Mean [SE] (95% CI)	-0.52 [0.20] (-0.91, -0.13)	-0.88 [0.18] (-1.24, -0.52)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.36 [0.26] (-0.14, 0.87)		
MMRM: P-value	0.16		
Corrected Hedges' g (95% CI)	0.209 (-0.098, 0.515)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.27		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-tss-item-gba.sas V.03.05 Output file: t-chg-tss-item-gba.pdf 29AUG2023: 9:49

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Tiredness at Week 8 from Baseline			
n	70	90	
Mean (SD)	-8.1 (50.89)	-14.7 (69.95)	
Median	-16.6	-19.7	
Q1, Q3	-41.1, 4.5	-47.8, 5.1	
Min, Max	-100.0, 203.6	-100.0, 475.0	
Difference in Percent Change from Baseline at Week 8			
n [1]	75	92	
n [2]	70	90	
MMRM: Least Squares Mean [SE] (95% CI)	-8.37 [7.67] (-23.51, 6.78)	-14.45 [6.89] (-28.05, -0.85)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	6.08 [9.76] (-13.20, 25.36)		
MMRM: P-value	0.53		
Corrected Hedges' g (95% CI)	0.093 (-0.219, 0.406)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.35		
Tiredness at Week 12			
n	74	90	
Mean (SD)	3.6 (2.36)	3.1 (2.27)	
Median	3.3	2.9	
Q1, Q3	1.9, 5.1	1.3, 4.2	
Min, Max	0.0, 9.3	0.0, 9.1	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Tiredness at Week 12 from Baseline			
n	73	89	
Mean (SD)	-0.8 (1.76)	-1.0 (1.96)	
Median	-0.5	-0.7	
Q1, Q3	-2.1, 0.4	-1.8, 0.1	
Min, Max	-5.2, 3.6	-6.9, 4.7	
Difference in Change from Baseline at Week 12			
n [1]	80	93	
n [2]	73	89	
MMRM: Least Squares Mean [SE] (95% CI)	-0.72 [0.21] (-1.12, -0.31)	-0.94 [0.19] (-1.31, -0.56)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.22 [0.27] (-0.31, 0.75)		
MMRM: P-value	0.41		
Corrected Hedges' g (95% CI)	0.124 (-0.186, 0.434)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.51		
Percent Change in Tiredness at Week 12 from Baseline			
n	68	88	
Mean (SD)	-6.9 (76.88)	-13.2 (102.29)	
Median	-22.6	-25.7	
Q1, Q3	-46.9, 4.6	-52.6, 2.8	
Min, Max	-100.0, 425.0	-100.0, 825.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Percent Change from Baseline at Week 12		
n [1]	75	92
n [2]	68	88
MMRM: Least Squares Mean [SE] (95% CI)	-7.65 [11.02] (-29.40, 14.11)	-12.07 [9.79] (-31.42, 7.27)
MMRM: Least Squares Mean Difference [SE] (95% CI)	4.42 [14.36] (-23.93, 32.78)	
MMRM: P-value	0.76	
Corrected Hedges' g (95% CI)	0.048 (-0.268, 0.365)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.39	
Tiredness at Week 16		
n	74	86
Mean (SD)	3.6 (2.23)	2.9 (2.15)
Median	3.4	2.8
Q1, Q3	1.9, 4.8	1.1, 4.1
Min, Max	0.0, 9.9	0.0, 8.2
Change in Tiredness at Week 16 from Baseline		
n	73	85
Mean (SD)	-0.8 (1.79)	-1.0 (1.96)
Median	-0.6	-0.6
Q1, Q3	-2.0, 0.4	-1.5, 0.3
Min, Max	-5.0, 3.6	-8.2, 2.4

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Change from Baseline at Week 16		
n [1]	80	93
n [2]	73	85
MMRM: Least Squares Mean [SE] (95% CI)	-0.77 [0.21] (-1.18, -0.36)	-1.02 [0.19] (-1.40, -0.64)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.25 [0.27] (-0.28, 0.78)	
MMRM: P-value	0.36	
Corrected Hedges' g (95% CI)	0.140 (-0.173, 0.453)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.65	
Percent Change in Tiredness at Week 16 from Baseline		
n	68	84
Mean (SD)	-3.9 (77.68)	-16.9 (64.21)
Median	-19.8	-23.6
Q1, Q3	-42.6, 14.4	-49.8, 13.9
Min, Max	-100.0, 360.7	-100.0, 375.0
Difference in Percent Change from Baseline at Week 16		
n [1]	75	92
n [2]	68	84
MMRM: Least Squares Mean [SE] (95% CI)	-4.25 [8.47] (-20.98, 12.48)	-17.33 [7.59] (-32.32, -2.35)
MMRM: Least Squares Mean Difference [SE] (95% CI)	13.08 [10.88] (-8.41, 34.57)	
MMRM: P-value	0.23	
Corrected Hedges' g (95% CI)	0.187 (-0.134, 0.507)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.41	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Tiredness at Week 20			
n	72	87	
Mean (SD)	3.6 (2.40)	3.0 (2.17)	
Median	3.3	2.7	
Q1, Q3	1.9, 5.0	1.3, 4.0	
Min, Max	0.0, 10.0	0.0, 9.6	
Change in Tiredness at Week 20 from Baseline			
n	71	86	
Mean (SD)	-0.8 (1.87)	-0.9 (2.08)	
Median	-0.4	-0.7	
Q1, Q3	-2.2, 0.3	-1.9, 0.5	
Min, Max	-6.2, 4.0	-8.5, 4.5	
Difference in Change from Baseline at Week 20			
n [1]	80	93	
n [2]	71	86	
MMRM: Least Squares Mean [SE] (95% CI)	-0.73 [0.22] (-1.16, -0.29)	-0.98 [0.20] (-1.37, -0.58)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.25 [0.29] (-0.31, 0.82)		
MMRM: P-value	0.38		
Corrected Hedges' g (95% CI)	0.134 (-0.181, 0.449)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.51		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-tss-item-gba.sas V.03.05 Output file: t-chg-tss-item-gba.pdf 29AUG2023: 9:49

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Tiredness at Week 20 from Baseline		
n	66	85
Mean (SD)	-4.1 (77.27)	-9.8 (80.73)
Median	-18.4	-25.4
Q1, Q3	-41.0, 11.3	-53.4, 7.8
Min, Max	-100.0, 396.4	-100.0, 475.0
Difference in Percent Change from Baseline at Week 20		
n [1]	75	92
n [2]	66	85
MMRM: Least Squares Mean [SE] (95% CI)	-3.70 [9.42] (-22.31, 14.90)	-10.68 [8.41] (-27.28, 5.92)
MMRM: Least Squares Mean Difference [SE] (95% CI)	6.98 [12.18] (-17.08, 31.03)	
MMRM: P-value	0.57	
Corrected Hedges' g (95% CI)	0.090 (-0.232, 0.412)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.32	
Tiredness at Week 24		
n	67	80
Mean (SD)	3.2 (2.15)	2.8 (2.19)
Median	2.9	2.6
Q1, Q3	1.7, 5.0	1.1, 4.2
Min, Max	0.0, 10.0	0.0, 9.7

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Change in Tiredness at Week 24 from Baseline		
n	66	79
Mean (SD)	-0.9 (1.97)	-1.0 (2.04)
Median	-0.6	-0.9
Q1, Q3	-2.1, 0.4	-2.1, 0.3
Min, Max	-6.9, 3.8	-7.3, 4.5
Difference in Change from Baseline at Week 24		
n [1]	80	93
n [2]	66	79
MMRM: Least Squares Mean [SE] (95% CI)	-0.79 [0.22] (-1.22, -0.35)	-1.07 [0.20] (-1.46, -0.67)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.28 [0.29] (-0.29, 0.84)	
MMRM: P-value	0.33	
Corrected Hedges' g (95% CI)	0.155 (-0.172, 0.482)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.44	
Percent Change in Tiredness at Week 24 from Baseline		
n	61	78
Mean (SD)	-5.4 (76.58)	-19.3 (59.52)
Median	-27.0	-31.4
Q1, Q3	-39.2, 19.6	-55.7, 10.5
Min, Max	-100.0, 381.5	-100.0, 186.8

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Percent Change from Baseline at Week 24		
n [1]	75	92
n [2]	61	78
MMRM: Least Squares Mean [SE] (95% CI)	-6.26 [8.03] (-22.12, 9.59)	-20.31 [7.23] (-34.58, -6.03)
MMRM: Least Squares Mean Difference [SE] (95% CI)	14.04 [10.30] (-6.29, 34.38)	
MMRM: P-value	0.17	
Corrected Hedges' g (95% CI)	0.220 (-0.116, 0.556)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.20	
TSS Item: Early Satiety		
Early Satiety at Baseline		
n	85	93
Mean (SD)	3.2 (2.48)	2.8 (2.35)
Median	2.9	2.3
Q1, Q3	1.0, 5.4	1.0, 4.4
Min, Max	0.0, 8.6	0.0, 9.3
Early Satiety at Week 4		
n	79	92
Mean (SD)	2.8 (2.47)	2.3 (2.13)
Median	2.3	1.6
Q1, Q3	0.6, 4.4	0.3, 3.8
Min, Max	0.0, 9.0	0.0, 7.5

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Early Satiety at Week 4 from Baseline			
n	78	91	
Mean (SD)	-0.4 (1.15)	-0.6 (0.97)	
Median	-0.2	-0.5	
Q1, Q3	-1.0, 0.2	-1.0, 0.0	
Min, Max	-3.9, 3.2	-4.8, 2.0	
Difference in Change from Baseline at Week 4			
n [1]	80	93	
n [2]	78	91	
MMRM: Least Squares Mean [SE] (95% CI)	-0.36 [0.12] (-0.60, -0.12)	-0.48 [0.11] (-0.70, -0.25)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.12 [0.15] (-0.18, 0.41)		
MMRM: P-value	0.45		
Corrected Hedges' g (95% CI)	0.107 (-0.196, 0.409)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.59		
Percent Change in Early Satiety at Week 4 from Baseline			
n	67	79	
Mean (SD)	-16.7 (43.91)	-23.0 (44.68)	
Median	-14.3	-18.8	
Q1, Q3	-44.8, 3.4	-47.3, -3.4	
Min, Max	-100.0, 114.9	-100.0, 143.8	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Percent Change from Baseline at Week 4		
n [1]	69	81
n [2]	67	79
MMRM: Least Squares Mean [SE] (95% CI)	-19.23 [5.76] (-30.61, -7.84)	-21.06 [5.40] (-31.74, -10.39)
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.83 [7.32] (-12.64, 16.31)	
MMRM: P-value	0.80	
Corrected Hedges' g (95% CI)	0.038 (-0.287, 0.364)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.65	
Early Satiety at Week 8		
n	76	92
Mean (SD)	2.4 (2.43)	1.8 (1.87)
Median	1.5	1.2
Q1, Q3	0.2, 4.1	0.0, 3.0
Min, Max	0.0, 9.6	0.0, 6.9
Change in Early Satiety at Week 8 from Baseline		
n	75	91
Mean (SD)	-0.8 (1.81)	-1.0 (1.51)
Median	-0.5	-0.6
Q1, Q3	-1.7, 0.0	-1.6, 0.0
Min, Max	-6.4, 3.5	-6.3, 1.7

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-tss-item-gba.sas V.03.05 Output file: t-chg-tss-item-gba.pdf 29AUG2023: 9:49

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Change from Baseline at Week 8		
n [1]	80	93
n [2]	75	91
MMRM: Least Squares Mean [SE] (95% CI)	-0.74 [0.18] (-1.10, -0.38)	-0.90 [0.17] (-1.24, -0.57)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.17 [0.24] (-0.30, 0.64)	
MMRM: P-value	0.48	
Corrected Hedges' g (95% CI)	0.105 (-0.201, 0.411)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.82	
Percent Change in Early Satiety at Week 8 from Baseline		
n	64	79
Mean (SD)	-27.1 (60.01)	-36.2 (47.82)
Median	-33.8	-34.4
Q1, Q3	-67.3, -2.7	-77.9, -11.0
Min, Max	-100.0, 163.7	-100.0, 135.0
Difference in Percent Change from Baseline at Week 8		
n [1]	69	81
n [2]	64	79
MMRM: Least Squares Mean [SE] (95% CI)	-29.30 [6.94] (-43.03, -15.58)	-34.00 [6.38] (-46.62, -21.39)
MMRM: Least Squares Mean Difference [SE] (95% CI)	4.70 [8.96] (-13.01, 22.41)	
MMRM: P-value	0.60	
Corrected Hedges' g (95% CI)	0.083 (-0.247, 0.413)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.57	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Early Satiety at Week 12			
n	74	90	
Mean (SD)	2.1 (2.34)	1.6 (1.76)	
Median	1.3	1.2	
Q1, Q3	0.0, 3.4	0.0, 2.5	
Min, Max	0.0, 9.3	0.0, 8.7	
Change in Early Satiety at Week 12 from Baseline			
n	73	89	
Mean (SD)	-1.0 (1.89)	-1.1 (1.69)	
Median	-0.8	-0.7	
Q1, Q3	-2.0, 0.0	-1.6, 0.0	
Min, Max	-6.0, 4.6	-8.0, 0.9	
Difference in Change from Baseline at Week 12			
n [1]	80	93	
n [2]	73	89	
MMRM: Least Squares Mean [SE] (95% CI)	-0.93 [0.20] (-1.33, -0.54)		-1.04 [0.18] (-1.41, -0.68)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.11 [0.26] (-0.41, 0.63)		
MMRM: P-value	0.68		
Corrected Hedges' g (95% CI)	0.062 (-0.247, 0.372)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.83		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Early Satiety at Week 12 from Baseline			
n	62	77	
Mean (SD)	-26.3 (91.77)	-39.9 (51.16)	
Median	-41.3	-42.0	
Q1, Q3	-75.0, -7.3	-86.5, -17.3	
Min, Max	-100.0, 451.5	-100.0, 150.0	
Difference in Percent Change from Baseline at Week 12			
n [1]	69	81	
n [2]	62	77	
MMRM: Least Squares Mean [SE] (95% CI)	-26.75 [9.47] (-45.47, -8.03)	-36.56 [8.62] (-53.61, -19.51)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	9.81 [12.46] (-14.82, 34.44)		
MMRM: P-value	0.43		
Corrected Hedges' g (95% CI)	0.130 (-0.205, 0.465)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.78		
Early Satiety at Week 16			
n	74	86	
Mean (SD)	2.1 (2.42)	1.5 (1.71)	
Median	1.4	0.9	
Q1, Q3	0.0, 3.4	0.0, 2.3	
Min, Max	0.0, 9.8	0.0, 8.6	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Early Satiety at Week 16 from Baseline			
n	73	85	
Mean (SD)	-0.9 (1.97)	-1.2 (1.82)	
Median	-0.4	-0.8	
Q1, Q3	-1.7, 0.0	-1.8, 0.0	
Min, Max	-6.4, 4.3	-9.3, 1.5	
Difference in Change from Baseline at Week 16			
n [1]	80	93	
n [2]	73	85	
MMRM: Least Squares Mean [SE] (95% CI)	-0.89 [0.21] (-1.31, -0.47)	-1.13 [0.19] (-1.52, -0.75)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.24 [0.28] (-0.31, 0.79)		
MMRM: P-value	0.39		
Corrected Hedges' g (95% CI)	0.132 (-0.181, 0.445)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.33		
Percent Change in Early Satiety at Week 16 from Baseline			
n	62	73	
Mean (SD)	-22.9 (88.84)	-42.1 (50.44)	
Median	-38.7	-44.7	
Q1, Q3	-89.1, 3.8	-90.8, -10.9	
Min, Max	-100.0, 419.7	-100.0, 110.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Percent Change from Baseline at Week 16		
n [1]	69	81
n [2]	62	73
MMRM: Least Squares Mean [SE] (95% CI)	-23.56 [9.31] (-41.97, -5.16)	-39.70 [8.49] (-56.48, -22.91)
MMRM: Least Squares Mean Difference [SE] (95% CI)	16.13 [12.25] (-8.09, 40.35)	
MMRM: P-value	0.19	
Corrected Hedges' g (95% CI)	0.220 (-0.119, 0.560)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.33	
Early Satiety at Week 20		
n	72	87
Mean (SD)	2.1 (2.44)	1.4 (1.67)
Median	1.4	1.0
Q1, Q3	0.0, 3.0	0.0, 2.1
Min, Max	0.0, 10.0	0.0, 8.8
Change in Early Satiety at Week 20 from Baseline		
n	71	86
Mean (SD)	-1.0 (1.98)	-1.2 (1.81)
Median	-0.4	-0.8
Q1, Q3	-1.7, 0.1	-1.8, 0.0
Min, Max	-7.3, 4.3	-9.3, 0.9

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Change from Baseline at Week 20		
n [1]	80	93
n [2]	71	86
MMRM: Least Squares Mean [SE] (95% CI)	-0.91 [0.21] (-1.33, -0.49)	-1.17 [0.19] (-1.55, -0.79)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.26 [0.28] (-0.29, 0.81)	
MMRM: P-value	0.36	
Corrected Hedges' g (95% CI)	0.143 (-0.171, 0.458)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.37	
Percent Change in Early Satiety at Week 20 from Baseline		
n	60	74
Mean (SD)	-34.5 (60.40)	-41.6 (48.25)
Median	-46.6	-38.7
Q1, Q3	-90.8, 3.4	-90.5, -20.5
Min, Max	-100.0, 167.1	-100.0, 107.4
Difference in Percent Change from Baseline at Week 20		
n [1]	69	81
n [2]	60	74
MMRM: Least Squares Mean [SE] (95% CI)	-29.27 [8.37] (-45.82, -12.72)	-40.32 [7.65] (-55.45, -25.19)
MMRM: Least Squares Mean Difference [SE] (95% CI)	11.04 [10.95] (-10.61, 32.70)	
MMRM: P-value	0.32	
Corrected Hedges' g (95% CI)	0.168 (-0.173, 0.509)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.53	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Early Satiety at Week 24			
n	67	80	
Mean (SD)	1.9 (2.24)	1.3 (1.67)	
Median	1.0	0.8	
Q1, Q3	0.0, 3.0	0.0, 2.2	
Min, Max	0.0, 10.0	0.0, 9.0	
Change in Early Satiety at Week 24 from Baseline			
n	66	79	
Mean (SD)	-0.9 (1.90)	-1.2 (1.91)	
Median	-0.3	-0.9	
Q1, Q3	-1.7, 0.1	-1.7, 0.0	
Min, Max	-7.3, 3.3	-8.9, 2.3	
Difference in Change from Baseline at Week 24			
n [1]	80	93	
n [2]	66	79	
MMRM: Least Squares Mean [SE] (95% CI)	-0.86 [0.22] (-1.30, -0.43)	-1.16 [0.20] (-1.56, -0.76)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.29 [0.29] (-0.28, 0.87)		
MMRM: P-value	0.31		
Corrected Hedges' g (95% CI)	0.163 (-0.164, 0.491)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.36		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Early Satiety at Week 24 from Baseline		
n	55	67
Mean (SD)	-24.6 (87.69)	-42.9 (57.23)
Median	-42.0	-46.2
Q1, Q3	-97.2, 7.1	-96.3, -19.4
Min, Max	-100.0, 324.2	-100.0, 183.3
Difference in Percent Change from Baseline at Week 24		
n [1]	69	81
n [2]	55	67
MMRM: Least Squares Mean [SE] (95% CI)	-22.04 [9.79] (-41.38, -2.69)	-40.44 [8.93] (-58.08, -22.79)
MMRM: Least Squares Mean Difference [SE] (95% CI)	18.40 [12.91] (-7.13, 43.93)	
MMRM: P-value	0.16	
Corrected Hedges' g (95% CI)	0.251 (-0.107, 0.609)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.34	
TSS Item: Abdominal Discomfort		
Abdominal Discomfort at Baseline		
n	85	93
Mean (SD)	2.6 (2.45)	2.9 (2.45)
Median	2.4	2.6
Q1, Q3	0.0, 4.6	0.8, 4.0
Min, Max	0.0, 9.0	0.0, 10.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Abdominal Discomfort at Week 4			
n	79	92	
Mean (SD)	2.4 (2.40)	2.4 (2.20)	
Median	1.6	1.9	
Q1, Q3	0.2, 3.5	0.7, 3.5	
Min, Max	0.0, 9.0	0.0, 9.0	
Change in Abdominal Discomfort at Week 4 from Baseline			
n	78	91	
Mean (SD)	-0.3 (1.06)	-0.4 (1.10)	
Median	-0.2	-0.3	
Q1, Q3	-0.9, 0.1	-1.0, 0.3	
Min, Max	-4.6, 2.7	-3.0, 2.9	
Difference in Change from Baseline at Week 4			
n [1]	80	93	
n [2]	78	91	
MMRM: Least Squares Mean [SE] (95% CI)	-0.29 [0.12] (-0.53, -0.04)	-0.29 [0.12] (-0.53, -0.06)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.01 [0.16] (-0.30, 0.32)		
MMRM: P-value	0.97		
Corrected Hedges' g (95% CI)	0.005 (-0.297, 0.308)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.81		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Abdominal Discomfort at Week 4 from Baseline		
n	59	81
Mean (SD)	-15.3 (59.85)	11.8 (234.80)
Median	-20.7	-18.5
Q1, Q3	-43.5, -1.7	-37.9, 8.6
Min, Max	-100.0, 352.6	-100.0, 2024.1
Difference in Percent Change from Baseline at Week 4		
n [1]	61	83
n [2]	59	81
MMRM: Least Squares Mean [SE] (95% CI)	-11.86 [24.09] (-59.50, 35.78)	16.63 [20.90] (-24.71, 57.97)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-28.49 [30.94] (-89.68, 32.71)	
MMRM: P-value	0.36	
Corrected Hedges' g (95% CI)	-0.152 (-0.488, 0.184)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.45	
Abdominal Discomfort at Week 8		
n	76	92
Mean (SD)	2.2 (2.31)	2.0 (1.88)
Median	1.3	1.4
Q1, Q3	0.3, 3.1	0.4, 3.1
Min, Max	0.0, 9.3	0.0, 8.8

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Change in Abdominal Discomfort at Week 8 from Baseline		
n	75	91
Mean (SD)	-0.6 (1.45)	-0.9 (1.70)
Median	-0.4	-0.5
Q1, Q3	-1.2, 0.1	-1.5, 0.1
Min, Max	-5.4, 2.1	-8.0, 3.7
Difference in Change from Baseline at Week 8		
n [1]	80	93
n [2]	75	91
MMRM: Least Squares Mean [SE] (95% CI)	-0.55 [0.17] (-0.88, -0.22)	-0.75 [0.16] (-1.06, -0.45)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.20 [0.22] (-0.23, 0.63)	
MMRM: P-value	0.36	
Corrected Hedges' g (95% CI)	0.135 (-0.171, 0.441)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.43	
Percent Change in Abdominal Discomfort at Week 8 from Baseline		
n	58	81
Mean (SD)	-18.3 (75.43)	16.2 (307.73)
Median	-26.9	-30.8
Q1, Q3	-67.3, -7.3	-50.0, -1.5
Min, Max	-100.0, 362.5	-100.0, 2622.2

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Percent Change from Baseline at Week 8		
n [1]	61	83
n [2]	58	81
MMRM: Least Squares Mean [SE] (95% CI)	-13.25 [31.14] (-74.83, 48.33)	22.07 [26.86] (-31.05, 75.18)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-35.32 [40.37] (-115.16, 44.52)	
MMRM: P-value	0.38	
Corrected Hedges' g (95% CI)	-0.146 (-0.484, 0.191)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.88	
Abdominal Discomfort at Week 12		
n	74	90
Mean (SD)	2.1 (2.28)	1.9 (1.79)
Median	1.5	1.3
Q1, Q3	0.1, 3.1	0.3, 3.0
Min, Max	0.0, 9.0	0.0, 8.0
Change in Abdominal Discomfort at Week 12 from Baseline		
n	73	89
Mean (SD)	-0.6 (1.57)	-0.9 (1.78)
Median	-0.4	-0.6
Q1, Q3	-1.3, 0.1	-2.0, 0.0
Min, Max	-5.0, 3.9	-7.2, 4.6

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-tss-item-gba.sas V.03.05 Output file: t-chg-tss-item-gba.pdf 29AUG2023: 9:49

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 12			
n [1]	80	93	
n [2]	73	89	
MMRM: Least Squares Mean [SE] (95% CI)	-0.57 [0.18] (-0.92, -0.22)	-0.81 [0.16] (-1.14, -0.49)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.24 [0.23] (-0.21, 0.70)		
MMRM: P-value	0.29		
Corrected Hedges' g (95% CI)	0.158 (-0.152, 0.468)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.20		
Percent Change in Abdominal Discomfort at Week 12 from Baseline			
n	56	79	
Mean (SD)	-20.1 (80.03)	39.5 (417.04)	
Median	-24.2	-32.1	
Q1, Q3	-63.7, -2.9	-70.0, -6.6	
Min, Max	-100.0, 438.0	-100.0, 3225.0	
Difference in Percent Change from Baseline at Week 12			
n [1]	61	83	
n [2]	56	79	
MMRM: Least Squares Mean [SE] (95% CI)	-15.49 [41.57] (-97.70, 66.72)	44.31 [35.59] (-26.08, 114.70)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-59.80 [54.16] (-166.90, 47.30)		
MMRM: P-value	0.27		
Corrected Hedges' g (95% CI)	-0.189 (-0.532, 0.154)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.75		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Abdominal Discomfort at Week 16			
n	74	86	
Mean (SD)	2.1 (2.42)	1.6 (1.77)	
Median	1.6	1.1	
Q1, Q3	0.1, 3.2	0.1, 2.6	
Min, Max	0.0, 9.9	0.0, 8.0	
Change in Abdominal Discomfort at Week 16 from Baseline			
n	73	85	
Mean (SD)	-0.6 (1.70)	-1.1 (1.94)	
Median	-0.3	-0.6	
Q1, Q3	-1.3, 0.3	-2.3, 0.1	
Min, Max	-7.0, 3.5	-8.1, 3.8	
Difference in Change from Baseline at Week 16			
n [1]	80	93	
n [2]	73	85	
MMRM: Least Squares Mean [SE] (95% CI)	-0.55 [0.19] (-0.93, -0.16)	-0.97 [0.18] (-1.32, -0.61)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.42 [0.25] (-0.08, 0.92)		
MMRM: P-value	0.10		
Corrected Hedges' g (95% CI)	0.252 (-0.062, 0.566)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.065		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Abdominal Discomfort at Week 16 from Baseline		
n	56	76
Mean (SD)	-19.9 (90.49)	3.1 (312.37)
Median	-32.6	-41.7
Q1, Q3	-78.6, 2.8	-83.3, -2.1
Min, Max	-100.0, 487.5	-100.0, 2625.0
Difference in Percent Change from Baseline at Week 16		
n [1]	61	83
n [2]	56	76
MMRM: Least Squares Mean [SE] (95% CI)	-14.86 [31.02] (-76.20, 46.49)	6.38 [26.74] (-46.50, 59.27)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-21.24 [40.21] (-100.75, 58.27)	
MMRM: P-value	0.60	
Corrected Hedges' g (95% CI)	-0.091 (-0.436, 0.255)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.49	
Abdominal Discomfort at Week 20		
n	72	87
Mean (SD)	2.0 (2.35)	1.7 (1.68)
Median	1.4	1.2
Q1, Q3	0.0, 3.2	0.1, 2.9
Min, Max	0.0, 10.0	0.0, 8.5

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Abdominal Discomfort at Week 20 from Baseline			
n	71	86	
Mean (SD)	-0.6 (1.73)	-1.1 (1.92)	
Median	-0.3	-0.7	
Q1, Q3	-1.3, 0.0	-2.1, 0.0	
Min, Max	-7.7, 3.3	-8.3, 3.3	
Difference in Change from Baseline at Week 20			
n [1]	80	93	
n [2]	71	86	
MMRM: Least Squares Mean [SE] (95% CI)	-0.58 [0.19] (-0.96, -0.20)	-0.98 [0.18] (-1.33, -0.63)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.40 [0.25] (-0.10, 0.89)		
MMRM: P-value	0.12		
Corrected Hedges' g (95% CI)	0.242 (-0.073, 0.558)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.12		
Percent Change in Abdominal Discomfort at Week 20 from Baseline			
n	54	77	
Mean (SD)	-26.0 (83.26)	3.3 (276.37)	
Median	-28.8	-37.1	
Q1, Q3	-88.5, -4.0	-78.6, -5.0	
Min, Max	-100.0, 406.3	-100.0, 2300.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Percent Change from Baseline at Week 20		
n [1]	61	83
n [2]	54	77
MMRM: Least Squares Mean [SE] (95% CI)	-19.31 [27.87] (-74.43, 35.80)	7.16 [24.06] (-40.42, 54.74)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-26.47 [35.99] (-97.64, 44.70)	
MMRM: P-value	0.46	
Corrected Hedges' g (95% CI)	-0.126 (-0.474, 0.222)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.79	
Abdominal Discomfort at Week 24		
n	67	80
Mean (SD)	1.8 (2.18)	1.5 (1.68)
Median	1.0	1.1
Q1, Q3	0.0, 2.9	0.0, 2.2
Min, Max	0.0, 10.0	0.0, 7.8
Change in Abdominal Discomfort at Week 24 from Baseline		
n	66	79
Mean (SD)	-0.6 (1.69)	-1.1 (1.83)
Median	-0.1	-0.8
Q1, Q3	-1.2, 0.1	-1.9, 0.0
Min, Max	-7.7, 2.9	-7.7, 2.7

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Change from Baseline at Week 24		
n [1]	80	93
n [2]	66	79
MMRM: Least Squares Mean [SE] (95% CI)	-0.56 [0.19] (-0.93, -0.18)	-1.02 [0.18] (-1.36, -0.67)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.46 [0.25] (-0.03, 0.95)	
MMRM: P-value	0.067	
Corrected Hedges' g (95% CI)	0.294 (-0.034, 0.623)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.049	
Percent Change in Abdominal Discomfort at Week 24 from Baseline		
n	49	70
Mean (SD)	-24.4 (94.43)	-7.9 (219.78)
Median	-37.8	-42.2
Q1, Q3	-90.2, 2.9	-75.0, -11.2
Min, Max	-100.0, 502.8	-100.0, 1700.0
Difference in Percent Change from Baseline at Week 24		
n [1]	61	83
n [2]	49	70
MMRM: Least Squares Mean [SE] (95% CI)	-18.33 [22.32] (-62.47, 25.80)	-4.58 [19.43] (-43.00, 33.84)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-13.75 [28.58] (-70.27, 42.76)	
MMRM: P-value	0.63	
Corrected Hedges' g (95% CI)	-0.085 (-0.451, 0.280)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.52	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
TSS Item: Night Sweats		
Night Sweats at Baseline		
n	85	93
Mean (SD)	2.2 (2.46)	2.4 (2.28)
Median	1.4	2.1
Q1, Q3	0.0, 3.3	0.1, 3.7
Min, Max	0.0, 10.0	0.0, 8.9
Night Sweats at Week 4		
n	79	92
Mean (SD)	1.7 (2.05)	1.6 (1.93)
Median	1.0	1.0
Q1, Q3	0.1, 2.5	0.1, 2.2
Min, Max	0.0, 10.0	0.0, 8.1
Change in Night Sweats at Week 4 from Baseline		
n	78	91
Mean (SD)	-0.6 (1.34)	-0.7 (1.18)
Median	-0.2	-0.5
Q1, Q3	-0.9, 0.1	-1.2, 0.0
Min, Max	-6.8, 2.8	-5.0, 1.9

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Change from Baseline at Week 4		
n [1]	80	93
n [2]	78	91
MMRM: Least Squares Mean [SE] (95% CI)	-0.56 [0.13] (-0.81, -0.30)	-0.69 [0.12] (-0.93, -0.45)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.13 [0.16] (-0.19, 0.46)	
MMRM: P-value	0.41	
Corrected Hedges' g (95% CI)	0.115 (-0.188, 0.418)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.10	
Percent Change in Night Sweats at Week 4 from Baseline		
n	60	70
Mean (SD)	6.5 (143.77)	-36.0 (39.70)
Median	-26.5	-42.1
Q1, Q3	-48.0, 2.2	-64.4, -10.9
Min, Max	-100.0, 750.0	-100.0, 93.1
Difference in Percent Change from Baseline at Week 4		
n [1]	61	72
n [2]	60	70
MMRM: Least Squares Mean [SE] (95% CI)	8.99 [13.92] (-18.56, 36.55)	-31.65 [13.39] (-58.14, -5.15)
MMRM: Least Squares Mean Difference [SE] (95% CI)	40.64 [17.46] (6.07, 75.20)	
MMRM: P-value	0.022	
Corrected Hedges' g (95% CI)	0.367 (0.019, 0.715)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.026	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Night Sweats at Week 8			
n	76	92	
Mean (SD)	1.5 (1.95)	1.3 (1.87)	
Median	0.7	0.4	
Q1, Q3	0.1, 2.4	0.0, 1.7	
Min, Max	0.0, 10.0	0.0, 7.9	
Change in Night Sweats at Week 8 from Baseline			
n	75	91	
Mean (SD)	-0.8 (1.51)	-1.1 (1.52)	
Median	-0.4	-0.6	
Q1, Q3	-1.6, 0.1	-1.9, 0.0	
Min, Max	-6.0, 3.4	-5.3, 2.7	
Difference in Change from Baseline at Week 8			
n [1]	80	93	
n [2]	75	91	
MMRM: Least Squares Mean [SE] (95% CI)	-0.77 [0.15] (-1.07, -0.48)	-1.04 [0.14] (-1.31, -0.77)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.27 [0.19] (-0.11, 0.65)		
MMRM: P-value	0.16		
Corrected Hedges' g (95% CI)	0.204 (-0.103, 0.510)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.14		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Night Sweats at Week 8 from Baseline		
n	58	70
Mean (SD)	-0.6 (146.50)	-51.6 (46.45)
Median	-41.0	-58.7
Q1, Q3	-66.7, -1.6	-93.4, -25.0
Min, Max	-100.0, 650.0	-100.0, 111.8
Difference in Percent Change from Baseline at Week 8		
n [1]	61	72
n [2]	58	70
MMRM: Least Squares Mean [SE] (95% CI)	1.04 [14.40] (-27.46, 29.54)	-47.29 [13.60] (-74.21, -20.37)
MMRM: Least Squares Mean Difference [SE] (95% CI)	48.33 [18.05] (12.61, 84.06)	
MMRM: P-value	0.008	
Corrected Hedges' g (95% CI)	0.429 (0.077, 0.781)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.015	
Night Sweats at Week 12		
n	74	90
Mean (SD)	1.4 (1.91)	1.2 (1.82)
Median	0.6	0.3
Q1, Q3	0.0, 2.1	0.0, 2.0
Min, Max	0.0, 10.0	0.0, 7.5

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Night Sweats at Week 12 from Baseline			
n	73	89	
Mean (SD)	-0.9 (1.88)	-1.1 (1.50)	
Median	-0.5	-0.7	
Q1, Q3	-1.5, 0.0	-1.9, 0.0	
Min, Max	-8.0, 4.2	-5.4, 2.1	
Difference in Change from Baseline at Week 12			
n [1]	80	93	
n [2]	73	89	
MMRM: Least Squares Mean [SE] (95% CI)	-0.89 [0.16] (-1.22, -0.57)	-1.10 [0.15] (-1.40, -0.80)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.21 [0.21] (-0.21, 0.62)		
MMRM: P-value	0.33		
Corrected Hedges' g (95% CI)	0.145 (-0.165, 0.455)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.41		
Percent Change in Night Sweats at Week 12 from Baseline			
n	56	68	
Mean (SD)	-0.2 (207.67)	-53.1 (47.83)	
Median	-46.9	-63.7	
Q1, Q3	-79.3, -16.6	-98.0, -22.7	
Min, Max	-100.0, 1275.0	-100.0, 100.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Percent Change from Baseline at Week 12		
n [1]	61	72
n [2]	56	68
MMRM: Least Squares Mean [SE] (95% CI)	2.66 [19.39] (-35.72, 41.04)	-49.19 [17.97] (-84.74, -13.63)
MMRM: Least Squares Mean Difference [SE] (95% CI)	51.84 [25.15] (2.06, 101.62)	
MMRM: P-value	0.041	
Corrected Hedges' g (95% CI)	0.351 (-0.005, 0.707)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.078	
Night Sweats at Week 16		
n	74	86
Mean (SD)	1.4 (2.04)	1.3 (1.78)
Median	0.4	0.3
Q1, Q3	0.0, 2.1	0.0, 2.0
Min, Max	0.0, 10.0	0.0, 6.6
Change in Night Sweats at Week 16 from Baseline		
n	73	85
Mean (SD)	-0.9 (1.99)	-1.1 (1.61)
Median	-0.4	-0.9
Q1, Q3	-2.0, 0.0	-1.9, 0.0
Min, Max	-8.5, 4.3	-5.4, 2.7

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Change from Baseline at Week 16		
n [1]	80	93
n [2]	73	85
MMRM: Least Squares Mean [SE] (95% CI)	-0.88 [0.18] (-1.23, -0.54)	-1.06 [0.16] (-1.38, -0.74)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.18 [0.23] (-0.27, 0.63)	
MMRM: P-value	0.44	
Corrected Hedges' g (95% CI)	0.118 (-0.195, 0.431)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.31	
Percent Change in Night Sweats at Week 16 from Baseline		
n	56	66
Mean (SD)	16.5 (235.14)	-51.5 (53.05)
Median	-49.3	-60.1
Q1, Q3	-93.4, -4.7	-98.6, -20.5
Min, Max	-100.0, 1429.6	-100.0, 120.8
Difference in Percent Change from Baseline at Week 16		
n [1]	61	72
n [2]	56	66
MMRM: Least Squares Mean [SE] (95% CI)	19.27 [21.55] (-23.38, 61.92)	-47.60 [19.89] (-86.98, -8.23)
MMRM: Least Squares Mean Difference [SE] (95% CI)	66.87 [28.18] (11.11, 122.64)	
MMRM: P-value	0.019	
Corrected Hedges' g (95% CI)	0.412 (0.052, 0.771)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.058	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Night Sweats at Week 20			
n	72	87	
Mean (SD)	1.4 (2.18)	1.2 (1.68)	
Median	0.4	0.4	
Q1, Q3	0.0, 2.0	0.0, 1.6	
Min, Max	0.0, 10.0	0.0, 6.9	
Change in Night Sweats at Week 20 from Baseline			
n	71	86	
Mean (SD)	-0.8 (2.03)	-1.2 (1.65)	
Median	-0.5	-0.9	
Q1, Q3	-2.0, 0.0	-2.2, 0.0	
Min, Max	-8.3, 4.4	-5.4, 2.1	
Difference in Change from Baseline at Week 20			
n [1]	80	93	
n [2]	71	86	
MMRM: Least Squares Mean [SE] (95% CI)	-0.81 [0.18] (-1.16, -0.45)	-1.17 [0.17] (-1.50, -0.84)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.36 [0.24] (-0.10, 0.82)		
MMRM: P-value	0.13		
Corrected Hedges' g (95% CI)	0.234 (-0.082, 0.549)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.27		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Night Sweats at Week 20 from Baseline		
n	54	67
Mean (SD)	34.9 (309.11)	-50.1 (55.76)
Median	-36.3	-61.0
Q1, Q3	-85.0, -16.6	-98.2, -25.8
Min, Max	-100.0, 1484.0	-100.0, 159.3
Difference in Percent Change from Baseline at Week 20		
n [1]	61	72
n [2]	54	67
MMRM: Least Squares Mean [SE] (95% CI)	36.83 [27.51] (-17.62, 91.27)	-46.91 [25.11] (-96.61, 2.78)
MMRM: Least Squares Mean Difference [SE] (95% CI)	83.74 [36.34] (11.82, 155.66)	
MMRM: P-value	0.023	
Corrected Hedges' g (95% CI)	0.408 (0.046, 0.770)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.043	
Night Sweats at Week 24		
n	67	80
Mean (SD)	1.1 (1.73)	1.0 (1.52)
Median	0.2	0.1
Q1, Q3	0.0, 2.0	0.0, 1.6
Min, Max	0.0, 7.0	0.0, 6.3

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Night Sweats at Week 24 from Baseline			
n	66	79	
Mean (SD)	-1.0 (2.14)	-1.1 (1.55)	
Median	-0.4	-0.9	
Q1, Q3	-2.0, 0.0	-2.2, 0.0	
Min, Max	-8.2, 5.5	-5.4, 1.4	
Difference in Change from Baseline at Week 24			
n [1]	80	93	
n [2]	66	79	
MMRM: Least Squares Mean [SE] (95% CI)	-0.89 [0.18] (-1.25, -0.52)	-1.18 [0.17] (-1.52, -0.85)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.30 [0.24] (-0.18, 0.77)		
MMRM: P-value	0.22		
Corrected Hedges' g (95% CI)	0.195 (-0.132, 0.523)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.75		
Percent Change in Night Sweats at Week 24 from Baseline			
n	49	61	
Mean (SD)	39.5 (366.11)	-58.8 (49.27)	
Median	-65.9	-81.5	
Q1, Q3	-98.1, -19.4	-100.0, -34.8	
Min, Max	-100.0, 2185.7	-100.0, 81.5	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Percent Change from Baseline at Week 24		
n [1]	61	72
n [2]	49	61
MMRM: Least Squares Mean [SE] (95% CI)	38.29 [31.12] (-23.31, 99.89)	-55.60 [28.38] (-111.78, 0.57)
MMRM: Least Squares Mean Difference [SE] (95% CI)	93.89 [41.32] (12.12, 175.66)	
MMRM: P-value	0.025	
Corrected Hedges' g (95% CI)	0.424 (0.044, 0.804)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.35	
TSS Item: Itching		
Itching at Baseline		
n	85	93
Mean (SD)	1.4 (2.18)	1.5 (2.04)
Median	0.1	0.6
Q1, Q3	0.0, 2.4	0.0, 2.3
Min, Max	0.0, 10.0	0.0, 8.7
Itching at Week 4		
n	79	92
Mean (SD)	1.2 (1.86)	1.0 (1.46)
Median	0.3	0.2
Q1, Q3	0.0, 2.0	0.0, 1.6
Min, Max	0.0, 10.0	0.0, 6.4

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Change in Itching at Week 4 from Baseline		
n	78	91
Mean (SD)	-0.2 (1.26)	-0.5 (1.30)
Median	0.0	0.0
Q1, Q3	-0.5, 0.0	-0.7, 0.0
Min, Max	-7.8, 2.7	-5.2, 1.9
Difference in Change from Baseline at Week 4		
n [1]	80	93
n [2]	78	91
MMRM: Least Squares Mean [SE] (95% CI)	-0.10 [0.12] (-0.34, 0.14)	-0.45 [0.12] (-0.68, -0.22)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.35 [0.15] (0.04, 0.65)	
MMRM: P-value	0.025	
Corrected Hedges' g (95% CI)	0.316 (0.011, 0.620)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.35	
Percent Change in Itching at Week 4 from Baseline		
n	42	58
Mean (SD)	11.9 (159.56)	-20.1 (97.60)
Median	-22.7	-37.5
Q1, Q3	-56.3, 0.0	-83.9, 2.0
Min, Max	-100.0, 841.4	-100.0, 500.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Percent Change from Baseline at Week 4		
n [1]	43	60
n [2]	42	58
MMRM: Least Squares Mean [SE] (95% CI)	18.21 [20.29] (-22.08, 58.50)	-13.27 [17.60] (-48.21, 21.66)
MMRM: Least Squares Mean Difference [SE] (95% CI)	31.49 [25.23] (-18.61, 81.58)	
MMRM: P-value	0.22	
Corrected Hedges' g (95% CI)	0.235 (-0.163, 0.633)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.61	
Itching at Week 8		
n	76	92
Mean (SD)	1.1 (1.76)	0.8 (1.33)
Median	0.3	0.0
Q1, Q3	0.0, 1.7	0.0, 1.1
Min, Max	0.0, 10.0	0.0, 6.3
Change in Itching at Week 8 from Baseline		
n	75	91
Mean (SD)	-0.2 (1.23)	-0.7 (1.76)
Median	0.0	0.0
Q1, Q3	-0.8, 0.1	-1.0, 0.0
Min, Max	-5.2, 3.2	-8.3, 2.4

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-tss-item-gba.sas V.03.05 Output file: t-chg-tss-item-gba.pdf 29AUG2023: 9:49

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Change from Baseline at Week 8		
n [1]	80	93
n [2]	75	91
MMRM: Least Squares Mean [SE] (95% CI)	-0.16 [0.15] (-0.45, 0.13)	-0.58 [0.14] (-0.86, -0.31)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.42 [0.19] (0.05, 0.80)	
MMRM: P-value	0.026	
Corrected Hedges' g (95% CI)	0.325 (0.018, 0.633)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.16	
Percent Change in Itching at Week 8 from Baseline		
n	40	58
Mean (SD)	35.4 (290.39)	-33.8 (95.91)
Median	-40.6	-64.6
Q1, Q3	-68.7, -3.2	-100.0, 0.0
Min, Max	-100.0, 1400.0	-100.0, 425.0
Difference in Percent Change from Baseline at Week 8		
n [1]	43	60
n [2]	40	58
MMRM: Least Squares Mean [SE] (95% CI)	39.77 [31.17] (-22.11, 101.65)	-26.42 [26.21] (-78.46, 25.62)
MMRM: Least Squares Mean Difference [SE] (95% CI)	66.19 [39.67] (-12.57, 144.95)	
MMRM: P-value	0.099	
Corrected Hedges' g (95% CI)	0.331 (-0.075, 0.736)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.16	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Itching at Week 12			
n	74	90	
Mean (SD)	1.2 (1.82)	0.8 (1.30)	
Median	0.5	0.1	
Q1, Q3	0.0, 2.0	0.0, 1.1	
Min, Max	0.0, 9.9	0.0, 5.6	
Change in Itching at Week 12 from Baseline			
n	73	89	
Mean (SD)	-0.1 (1.55)	-0.6 (1.70)	
Median	0.0	0.0	
Q1, Q3	-0.7, 0.0	-1.0, 0.0	
Min, Max	-6.5, 4.9	-8.2, 3.5	
Difference in Change from Baseline at Week 12			
n [1]	80	93	
n [2]	73	89	
MMRM: Least Squares Mean [SE] (95% CI)	-0.07 [0.16] (-0.38, 0.25)	-0.57 [0.15] (-0.86, -0.28)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.50 [0.21] (0.10, 0.91)		
MMRM: P-value	0.016		
Corrected Hedges' g (95% CI)	0.363 (0.051, 0.675)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.18		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Itching at Week 12 from Baseline		
n	38	56
Mean (SD)	48.5 (318.21)	-18.3 (137.64)
Median	-39.0	-63.4
Q1, Q3	-76.5, -1.1	-100.0, -1.6
Min, Max	-100.0, 1377.8	-100.0, 644.0
Difference in Percent Change from Baseline at Week 12		
n [1]	43	60
n [2]	38	56
MMRM: Least Squares Mean [SE] (95% CI)	48.55 [34.89] (-20.71, 117.81)	-13.53 [29.18] (-71.46, 44.39)
MMRM: Least Squares Mean Difference [SE] (95% CI)	62.08 [44.53] (-26.32, 150.48)	
MMRM: P-value	0.17	
Corrected Hedges' g (95% CI)	0.284 (-0.130, 0.698)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.17	
Itching at Week 16		
n	74	86
Mean (SD)	1.3 (2.00)	0.7 (1.25)
Median	0.2	0.0
Q1, Q3	0.0, 2.0	0.0, 1.0
Min, Max	0.0, 9.8	0.0, 5.1

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Itching at Week 16 from Baseline			
n	73	85	
Mean (SD)	0.0 (1.74)	-0.6 (1.62)	
Median	0.0	0.0	
Q1, Q3	-0.8, 0.2	-1.0, 0.0	
Min, Max	-7.6, 5.7	-6.8, 2.9	
Difference in Change from Baseline at Week 16			
n [1]	80	93	
n [2]	73	85	
MMRM: Least Squares Mean [SE] (95% CI)	0.00 [0.17] (-0.33, 0.33)	-0.62 [0.16] (-0.93, -0.32)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.62 [0.22] (0.19, 1.05)		
MMRM: P-value	0.005		
Corrected Hedges' g (95% CI)	0.431 (0.115, 0.748)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.071		
Percent Change in Itching at Week 16 from Baseline			
n	38	53	
Mean (SD)	63.8 (403.98)	-43.0 (74.32)	
Median	-46.2	-72.0	
Q1, Q3	-89.9, -2.5	-100.0, -15.6	
Min, Max	-100.0, 2250.0	-100.0, 188.6	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Percent Change from Baseline at Week 16		
n [1]	43	60
n [2]	38	53
MMRM: Least Squares Mean [SE] (95% CI)	62.78 [40.94] (-18.50, 144.06)	-41.12 [34.27] (-109.16, 26.92)
MMRM: Least Squares Mean Difference [SE] (95% CI)	103.90 [52.57] (-0.47, 208.27)	
MMRM: P-value	0.051	
Corrected Hedges' g (95% CI)	0.411 (-0.010, 0.832)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.12	
Itching at Week 20		
n	72	87
Mean (SD)	1.3 (2.16)	0.8 (1.28)
Median	0.2	0.0
Q1, Q3	0.0, 1.9	0.0, 1.3
Min, Max	0.0, 9.9	0.0, 4.9
Change in Itching at Week 20 from Baseline		
n	71	86
Mean (SD)	0.0 (1.83)	-0.6 (1.68)
Median	0.0	0.0
Q1, Q3	-0.6, 0.2	-1.0, 0.0
Min, Max	-7.3, 6.4	-6.7, 3.1

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Change from Baseline at Week 20		
n [1]	80	93
n [2]	71	86
MMRM: Least Squares Mean [SE] (95% CI)	0.06 [0.18] (-0.29, 0.41)	-0.57 [0.16] (-0.89, -0.25)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.63 [0.23] (0.18, 1.09)	
MMRM: P-value	0.007	
Corrected Hedges' g (95% CI)	0.419 (0.102, 0.737)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.095	
Percent Change in Itching at Week 20 from Baseline		
n	37	54
Mean (SD)	75.2 (467.71)	-42.4 (77.74)
Median	-38.8	-76.0
Q1, Q3	-100.0, -0.9	-100.0, -18.0
Min, Max	-100.0, 2625.0	-100.0, 217.1
Difference in Percent Change from Baseline at Week 20		
n [1]	43	60
n [2]	37	54
MMRM: Least Squares Mean [SE] (95% CI)	71.11 [46.56] (-21.32, 163.55)	-41.07 [38.94] (-118.37, 36.23)
MMRM: Least Squares Mean Difference [SE] (95% CI)	112.18 [59.96] (-6.86, 231.22)	
MMRM: P-value	0.064	
Corrected Hedges' g (95% CI)	0.390 (-0.032, 0.812)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.20	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Itching at Week 24			
n	67	80	
Mean (SD)	1.1 (1.89)	0.7 (1.22)	
Median	0.0	0.0	
Q1, Q3	0.0, 2.0	0.0, 1.2	
Min, Max	0.0, 7.9	0.0, 5.3	
Change in Itching at Week 24 from Baseline			
n	66	79	
Mean (SD)	0.0 (1.89)	-0.6 (1.53)	
Median	0.0	0.0	
Q1, Q3	-0.5, 0.0	-1.0, 0.0	
Min, Max	-7.9, 5.7	-4.9, 3.1	
Difference in Change from Baseline at Week 24			
n [1]	80	93	
n [2]	66	79	
MMRM: Least Squares Mean [SE] (95% CI)	0.07 [0.17] (-0.28, 0.41)	-0.64 [0.16] (-0.96, -0.32)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.71 [0.23] (0.26, 1.16)		
MMRM: P-value	0.002		
Corrected Hedges' g (95% CI)	0.493 (0.161, 0.824)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.17		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Itching at Week 24 from Baseline		
n	33	49
Mean (SD)	66.5 (491.88)	-43.8 (92.23)
Median	-43.1	-95.9
Q1, Q3	-96.2, 0.0	-100.0, -3.6
Min, Max	-100.0, 2700.0	-100.0, 387.5
Difference in Percent Change from Baseline at Week 24		
n [1]	43	60
n [2]	33	49
MMRM: Least Squares Mean [SE] (95% CI)	75.47 [48.23] (-20.28, 171.22)	-40.50 [40.30] (-120.50, 39.51)
MMRM: Least Squares Mean Difference [SE] (95% CI)	115.97 [62.14] (-7.39, 239.33)	
MMRM: P-value	0.065	
Corrected Hedges' g (95% CI)	0.410 (-0.036, 0.856)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.29	
TSS Item: Bone Pain		
Bone Pain at Baseline		
n	85	93
Mean (SD)	2.9 (2.95)	2.0 (2.30)
Median	2.3	1.3
Q1, Q3	0.0, 4.7	0.0, 3.1
Min, Max	0.0, 9.9	0.0, 8.7

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Bone Pain at Week 4			
n	79	92	
Mean (SD)	2.6 (2.89)	1.9 (2.02)	
Median	1.7	1.2	
Q1, Q3	0.1, 4.8	0.0, 3.1	
Min, Max	0.0, 10.0	0.0, 8.2	
Change in Bone Pain at Week 4 from Baseline			
n	78	91	
Mean (SD)	-0.3 (0.99)	-0.1 (1.26)	
Median	-0.1	0.0	
Q1, Q3	-0.9, 0.1	-0.4, 0.3	
Min, Max	-4.2, 2.2	-5.0, 3.7	
Difference in Change from Baseline at Week 4			
n [1]	80	93	
n [2]	78	91	
MMRM: Least Squares Mean [SE] (95% CI)	-0.28 [0.14] (-0.55, -0.01)	-0.22 [0.13] (-0.47, 0.03)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.06 [0.17] (-0.39, 0.27)		
MMRM: P-value	0.73		
Corrected Hedges' g (95% CI)	-0.049 (-0.351, 0.254)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.082		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Bone Pain at Week 4 from Baseline		
n	59	64
Mean (SD)	-1.5 (102.69)	1.8 (73.46)
Median	-9.7	-8.0
Q1, Q3	-37.1, 7.8	-40.0, 21.6
Min, Max	-97.5, 672.4	-100.0, 225.0
Difference in Percent Change from Baseline at Week 4		
n [1]	61	65
n [2]	59	64
MMRM: Least Squares Mean [SE] (95% CI)	-1.72 [12.39] (-26.25, 22.81)	0.20 [11.67] (-22.91, 23.32)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.93 [16.32] (-34.25, 30.40)	
MMRM: P-value	0.91	
Corrected Hedges' g (95% CI)	-0.020 (-0.374, 0.333)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.36	
Bone Pain at Week 8		
n	76	92
Mean (SD)	2.4 (2.85)	1.7 (1.90)
Median	1.5	1.0
Q1, Q3	0.0, 3.3	0.0, 2.8
Min, Max	0.0, 9.7	0.0, 7.9

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Bone Pain at Week 8 from Baseline			
n	75	91	
Mean (SD)	-0.5 (1.54)	-0.3 (1.73)	
Median	-0.1	0.0	
Q1, Q3	-1.5, 0.2	-0.7, 0.2	
Min, Max	-5.9, 5.4	-7.1, 4.2	
Difference in Change from Baseline at Week 8			
n [1]	80	93	
n [2]	75	91	
MMRM: Least Squares Mean [SE] (95% CI)	-0.51 [0.18] (-0.88, -0.15)	-0.33 [0.17] (-0.66, 0.00)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.18 [0.24] (-0.65, 0.28)		
MMRM: P-value	0.44		
Corrected Hedges' g (95% CI)	-0.114 (-0.420, 0.192)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.31		
Percent Change in Bone Pain at Week 8 from Baseline			
n	58	63	
Mean (SD)	8.8 (174.00)	3.8 (131.47)	
Median	-26.2	-19.1	
Q1, Q3	-63.0, 5.9	-58.2, 13.8	
Min, Max	-100.0, 1075.0	-100.0, 712.5	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Percent Change from Baseline at Week 8		
n [1]	61	65
n [2]	58	63
MMRM: Least Squares Mean [SE] (95% CI)	7.14 [20.21] (-32.88, 47.15)	2.98 [19.24] (-35.12, 41.08)
MMRM: Least Squares Mean Difference [SE] (95% CI)	4.16 [27.47] (-50.25, 58.56)	
MMRM: P-value	0.88	
Corrected Hedges' g (95% CI)	0.027 (-0.330, 0.384)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.56	
Bone Pain at Week 12		
n	74	90
Mean (SD)	2.1 (2.61)	1.7 (1.90)
Median	1.3	1.0
Q1, Q3	0.0, 3.0	0.0, 2.9
Min, Max	0.0, 8.9	0.0, 8.8
Change in Bone Pain at Week 12 from Baseline		
n	73	89
Mean (SD)	-0.8 (1.63)	-0.2 (1.77)
Median	-0.4	0.0
Q1, Q3	-1.4, 0.0	-0.6, 0.1
Min, Max	-6.6, 4.4	-8.2, 4.5

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Change from Baseline at Week 12		
n [1]	80	93
n [2]	73	89
MMRM: Least Squares Mean [SE] (95% CI)	-0.74 [0.19] (-1.11, -0.37)	-0.27 [0.17] (-0.61, 0.06)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.47 [0.24] (-0.94, 0.01)	
MMRM: P-value	0.053	
Corrected Hedges' g (95% CI)	-0.292 (-0.603, 0.019)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.020	
Percent Change in Bone Pain at Week 12 from Baseline		
n	56	61
Mean (SD)	18.4 (246.38)	12.8 (204.86)
Median	-33.8	-19.2
Q1, Q3	-58.9, -5.4	-50.0, 5.6
Min, Max	-100.0, 1300.0	-100.0, 1500.0
Difference in Percent Change from Baseline at Week 12		
n [1]	61	65
n [2]	56	61
MMRM: Least Squares Mean [SE] (95% CI)	15.16 [29.12] (-42.50, 72.82)	11.32 [27.71] (-43.54, 66.19)
MMRM: Least Squares Mean Difference [SE] (95% CI)	3.84 [39.89] (-75.16, 82.84)	
MMRM: P-value	0.92	
Corrected Hedges' g (95% CI)	0.018 (-0.345, 0.380)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.11	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Bone Pain at Week 16			
n	74	86	
Mean (SD)	2.0 (2.58)	1.6 (1.95)	
Median	1.1	0.9	
Q1, Q3	0.0, 2.5	0.0, 2.8	
Min, Max	0.0, 9.1	0.0, 8.9	
Change in Bone Pain at Week 16 from Baseline			
n	73	85	
Mean (SD)	-0.9 (1.88)	-0.3 (1.72)	
Median	-0.3	0.0	
Q1, Q3	-1.9, 0.0	-0.6, 0.0	
Min, Max	-7.6, 3.1	-8.1, 4.0	
Difference in Change from Baseline at Week 16			
n [1]	80	93	
n [2]	73	85	
MMRM: Least Squares Mean [SE] (95% CI)	-0.86 [0.20] (-1.26, -0.47)	-0.34 [0.18] (-0.71, 0.02)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.52 [0.26] (-1.03, 0.00)		
MMRM: P-value	0.048		
Corrected Hedges' g (95% CI)	-0.304 (-0.618, 0.011)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.091		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Bone Pain at Week 16 from Baseline		
n	56	59
Mean (SD)	26.3 (304.96)	-3.2 (142.89)
Median	-28.9	-22.2
Q1, Q3	-82.9, 3.7	-70.8, 7.3
Min, Max	-100.0, 1750.0	-100.0, 950.0
Difference in Percent Change from Baseline at Week 16		
n [1]	61	65
n [2]	56	59
MMRM: Least Squares Mean [SE] (95% CI)	22.84 [30.29] (-37.14, 82.83)	-8.11 [28.88] (-65.30, 49.08)
MMRM: Least Squares Mean Difference [SE] (95% CI)	30.96 [41.56] (-51.34, 113.26)	
MMRM: P-value	0.46	
Corrected Hedges' g (95% CI)	0.137 (-0.229, 0.503)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.34	
Bone Pain at Week 20		
n	72	87
Mean (SD)	2.0 (2.65)	1.6 (1.98)
Median	1.0	1.0
Q1, Q3	0.0, 2.7	0.0, 2.9
Min, Max	0.0, 9.1	0.0, 8.6

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Bone Pain at Week 20 from Baseline			
n	71	86	
Mean (SD)	-0.9 (1.84)	-0.3 (1.62)	
Median	-0.5	0.0	
Q1, Q3	-1.8, 0.0	-0.8, 0.0	
Min, Max	-7.5, 2.6	-5.7, 4.6	
Difference in Change from Baseline at Week 20			
n [1]	80	93	
n [2]	71	86	
MMRM: Least Squares Mean [SE] (95% CI)	-0.84 [0.20] (-1.22, -0.45)	-0.34 [0.18] (-0.70, 0.01)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.49 [0.25] (-0.99, 0.01)		
MMRM: P-value	0.053		
Corrected Hedges' g (95% CI)	-0.298 (-0.614, 0.018)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.075		
Percent Change in Bone Pain at Week 20 from Baseline			
n	54	60	
Mean (SD)	8.6 (250.22)	-12.4 (96.78)	
Median	-36.0	-24.3	
Q1, Q3	-97.7, 0.0	-74.9, 5.4	
Min, Max	-100.0, 1425.0	-100.0, 537.5	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Percent Change from Baseline at Week 20		
n [1]	61	65
n [2]	54	60
MMRM: Least Squares Mean [SE] (95% CI)	7.90 [24.02] (-39.66, 55.46)	-17.12 [22.87] (-62.42, 28.18)
MMRM: Least Squares Mean Difference [SE] (95% CI)	25.02 [32.81] (-39.95, 89.99)	
MMRM: P-value	0.45	
Corrected Hedges' g (95% CI)	0.141 (-0.228, 0.509)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.21	
Bone Pain at Week 24		
n	67	80
Mean (SD)	1.7 (2.37)	1.5 (1.85)
Median	0.7	0.9
Q1, Q3	0.0, 2.3	0.0, 2.5
Min, Max	0.0, 9.8	0.0, 7.9
Change in Bone Pain at Week 24 from Baseline		
n	66	79
Mean (SD)	-0.9 (1.90)	-0.3 (1.67)
Median	-0.6	0.0
Q1, Q3	-1.8, 0.0	-0.8, 0.1
Min, Max	-7.0, 3.5	-5.6, 3.8

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)		RUX (N=94)	
Difference in Change from Baseline at Week 24				
n [1]	80		93	
n [2]	66		79	
MMRM: Least Squares Mean [SE] (95% CI)	-0.82 [0.20] (-1.22, -0.41)		-0.34 [0.19] (-0.70, 0.03)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.48 [0.26] (-1.00, 0.04)			
MMRM: P-value	0.073			
Corrected Hedges' g (95% CI)	-0.288 (-0.617, 0.041)			
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.11			
Percent Change in Bone Pain at Week 24 from Baseline				
n	49		55	
Mean (SD)	9.3 (251.70)		9.5 (191.76)	
Median	-42.3		-24.1	
Q1, Q3	-94.3, -17.3		-84.6, 8.8	
Min, Max	-100.0, 1533.3		-100.0, 1225.0	
Difference in Percent Change from Baseline at Week 24				
n [1]	61		65	
n [2]	49		55	
MMRM: Least Squares Mean [SE] (95% CI)	3.88 [27.45] (-50.47, 58.23)		1.71 [26.08] (-49.94, 53.37)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	2.17 [37.53] (-72.15, 76.49)			
MMRM: P-value	0.95			
Corrected Hedges' g (95% CI)	0.011 (-0.374, 0.396)			
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.18			

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
TSS Item: Pain in Left Ribs		
Pain in Left Ribs at Baseline		
n	85	93
Mean (SD)	2.1 (2.35)	2.4 (2.55)
Median	1.1	1.4
Q1, Q3	0.0, 3.6	0.4, 3.6
Min, Max	0.0, 9.0	0.0, 10.0
Pain in Left Ribs at Week 4		
n	79	92
Mean (SD)	1.8 (2.07)	2.1 (2.19)
Median	1.2	1.4
Q1, Q3	0.0, 3.2	0.3, 3.0
Min, Max	0.0, 8.4	0.0, 9.0
Change in Pain in Left Ribs at Week 4 from Baseline		
n	78	91
Mean (SD)	-0.3 (0.92)	-0.3 (0.97)
Median	0.0	-0.2
Q1, Q3	-0.7, 0.0	-0.9, 0.1
Min, Max	-5.4, 1.6	-2.9, 3.1

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-tss-item-gba.sas V.03.05 Output file: t-chg-tss-item-gba.pdf 29AUG2023: 9:49

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Change from Baseline at Week 4		
n [1]	80	93
n [2]	78	91
MMRM: Least Squares Mean [SE] (95% CI)	-0.31 [0.10] (-0.51, -0.11)	-0.29 [0.10] (-0.48, -0.09)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.02 [0.13] (-0.28, 0.23)	
MMRM: P-value	0.86	
Corrected Hedges' g (95% CI)	-0.025 (-0.327, 0.278)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.39	
Percent Change in Pain in Left Ribs at Week 4 from Baseline		
n	54	77
Mean (SD)	-4.4 (94.66)	-18.1 (53.10)
Median	-20.9	-23.1
Q1, Q3	-35.4, 2.1	-51.7, 2.0
Min, Max	-100.0, 563.8	-100.0, 208.0
Difference in Percent Change from Baseline at Week 4		
n [1]	55	78
n [2]	54	77
MMRM: Least Squares Mean [SE] (95% CI)	2.75 [10.33] (-17.70, 23.19)	-12.08 [9.00] (-29.90, 5.74)
MMRM: Least Squares Mean Difference [SE] (95% CI)	14.82 [13.00] (-10.91, 40.55)	
MMRM: P-value	0.26	
Corrected Hedges' g (95% CI)	0.190 (-0.159, 0.538)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.39	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Pain in Left Ribs at Week 8			
n	76	92	
Mean (SD)	1.6 (2.07)	1.6 (1.85)	
Median	0.7	1.0	
Q1, Q3	0.0, 2.5	0.1, 2.7	
Min, Max	0.0, 8.2	0.0, 8.4	
Change in Pain in Left Ribs at Week 8 from Baseline			
n	75	91	
Mean (SD)	-0.6 (1.51)	-0.7 (1.77)	
Median	-0.2	-0.4	
Q1, Q3	-1.0, 0.0	-1.3, 0.0	
Min, Max	-8.6, 3.2	-7.1, 5.5	
Difference in Change from Baseline at Week 8			
n [1]	80	93	
n [2]	75	91	
MMRM: Least Squares Mean [SE] (95% CI)	-0.57 [0.16] (-0.89, -0.24)	-0.67 [0.15] (-0.97, -0.37)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.10 [0.22] (-0.33, 0.53)		
MMRM: P-value	0.65		
Corrected Hedges' g (95% CI)	0.069 (-0.237, 0.374)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.39		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Pain in Left Ribs at Week 8 from Baseline		
n	52	76
Mean (SD)	-35.3 (43.02)	-24.9 (79.00)
Median	-27.8	-39.1
Q1, Q3	-75.4, -6.2	-76.5, -7.1
Min, Max	-100.0, 74.7	-100.0, 369.0
Difference in Percent Change from Baseline at Week 8		
n [1]	55	78
n [2]	52	76
MMRM: Least Squares Mean [SE] (95% CI)	-27.69 [9.39] (-46.27, -9.11)	-18.15 [8.15] (-34.27, -2.02)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-9.54 [11.69] (-32.68, 13.60)	
MMRM: P-value	0.42	
Corrected Hedges' g (95% CI)	-0.136 (-0.489, 0.217)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.85	
Pain in Left Ribs at Week 12		
n	74	90
Mean (SD)	1.5 (2.10)	1.5 (1.81)
Median	0.5	0.9
Q1, Q3	0.0, 2.9	0.0, 2.5
Min, Max	0.0, 7.5	0.0, 8.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Change in Pain in Left Ribs at Week 12 from Baseline		
n	73	89
Mean (SD)	-0.5 (1.63)	-0.8 (1.83)
Median	0.0	-0.5
Q1, Q3	-1.1, 0.1	-1.3, 0.0
Min, Max	-7.5, 3.9	-7.8, 5.3
Difference in Change from Baseline at Week 12		
n [1]	80	93
n [2]	73	89
MMRM: Least Squares Mean [SE] (95% CI)	-0.52 [0.17] (-0.87, -0.18)	-0.72 [0.16] (-1.04, -0.41)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.20 [0.23] (-0.25, 0.65)	
MMRM: P-value	0.39	
Corrected Hedges' g (95% CI)	0.132 (-0.178, 0.442)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.033	
Percent Change in Pain in Left Ribs at Week 12 from Baseline		
n	50	74
Mean (SD)	-32.5 (57.82)	-31.6 (74.95)
Median	-35.2	-46.5
Q1, Q3	-88.5, 0.3	-77.8, -10.2
Min, Max	-100.0, 108.0	-100.0, 352.4

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Percent Change from Baseline at Week 12		
n [1]	55	78
n [2]	50	74
MMRM: Least Squares Mean [SE] (95% CI)	-25.06 [9.71] (-44.27, -5.84)	-24.21 [8.37] (-40.78, -7.63)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.85 [12.10] (-24.80, 23.10)	
MMRM: P-value	0.94	
Corrected Hedges' g (95% CI)	-0.012 (-0.371, 0.347)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.48	
Pain in Left Ribs at Week 16		
n	74	86
Mean (SD)	1.6 (2.18)	1.5 (1.85)
Median	0.6	0.7
Q1, Q3	0.0, 2.5	0.0, 2.5
Min, Max	0.0, 8.5	0.0, 8.0
Change in Pain in Left Ribs at Week 16 from Baseline		
n	73	85
Mean (SD)	-0.5 (1.75)	-0.9 (1.93)
Median	-0.1	-0.5
Q1, Q3	-1.0, 0.0	-1.4, 0.0
Min, Max	-8.0, 4.3	-8.1, 4.9

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)		RUX (N=94)	
Difference in Change from Baseline at Week 16				
n [1]	80		93	
n [2]	73		85	
MMRM: Least Squares Mean [SE] (95% CI)	-0.50 [0.19] (-0.87, -0.13)		-0.76 [0.17] (-1.10, -0.42)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.25 [0.25] (-0.24, 0.74)			
MMRM: P-value	0.31			
Corrected Hedges' g (95% CI)	0.158 (-0.155, 0.472)			
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.034			
Percent Change in Pain in Left Ribs at Week 16 from Baseline				
n	50		71	
Mean (SD)	-28.1 (60.14)		-30.5 (80.75)	
Median	-27.7		-43.3	
Q1, Q3	-88.9, -1.0		-85.3, -10.9	
Min, Max	-100.0, 120.1		-100.0, 328.6	
Difference in Percent Change from Baseline at Week 16				
n [1]	55		78	
n [2]	50		71	
MMRM: Least Squares Mean [SE] (95% CI)	-20.54 [10.30] (-40.92, -0.17)		-23.59 [8.86] (-41.12, -6.05)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	3.05 [12.91] (-22.50, 28.59)			
MMRM: P-value	0.81			
Corrected Hedges' g (95% CI)	0.041 (-0.321, 0.403)			
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.37			

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Pain in Left Ribs at Week 20			
n	72	87	
Mean (SD)	1.5 (2.33)	1.4 (1.75)	
Median	0.2	1.0	
Q1, Q3	0.0, 2.1	0.0, 2.3	
Min, Max	0.0, 9.9	0.0, 8.6	
Change in Pain in Left Ribs at Week 20 from Baseline			
n	71	86	
Mean (SD)	-0.6 (1.90)	-1.0 (2.01)	
Median	-0.1	-0.5	
Q1, Q3	-1.0, 0.0	-1.4, 0.0	
Min, Max	-8.1, 6.2	-8.1, 5.7	
Difference in Change from Baseline at Week 20			
n [1]	80	93	
n [2]	71	86	
MMRM: Least Squares Mean [SE] (95% CI)	-0.52 [0.20] (-0.92, -0.12)	-0.85 [0.18] (-1.21, -0.48)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.33 [0.27] (-0.20, 0.85)		
MMRM: P-value	0.22		
Corrected Hedges' g (95% CI)	0.190 (-0.125, 0.505)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.078		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Pain in Left Ribs at Week 20 from Baseline		
n	48	72
Mean (SD)	-38.4 (59.62)	-36.7 (79.33)
Median	-39.2	-49.7
Q1, Q3	-91.9, -1.8	-91.5, -12.5
Min, Max	-100.0, 167.3	-100.0, 381.5
Difference in Percent Change from Baseline at Week 20		
n [1]	55	78
n [2]	48	72
MMRM: Least Squares Mean [SE] (95% CI)	-25.99 [10.45] (-46.69, -5.30)	-30.16 [8.93] (-47.84, -12.48)
MMRM: Least Squares Mean Difference [SE] (95% CI)	4.16 [13.08] (-21.73, 30.06)	
MMRM: P-value	0.75	
Corrected Hedges' g (95% CI)	0.056 (-0.310, 0.421)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.63	
Pain in Left Ribs at Week 24		
n	67	80
Mean (SD)	1.3 (2.04)	1.2 (1.57)
Median	0.2	0.5
Q1, Q3	0.0, 2.2	0.0, 1.8
Min, Max	0.0, 9.8	0.0, 7.8

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Pain in Left Ribs at Week 24 from Baseline			
n	66	79	
Mean (SD)	-0.5 (1.47)	-1.2 (1.90)	
Median	-0.2	-0.6	
Q1, Q3	-1.1, 0.0	-1.5, 0.0	
Min, Max	-6.9, 3.5	-8.2, 2.1	
Difference in Change from Baseline at Week 24			
n [1]	80	93	
n [2]	66	79	
MMRM: Least Squares Mean [SE] (95% CI)	-0.49 [0.19] (-0.88, -0.11)		-0.97 [0.18] (-1.32, -0.62)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.47 [0.26] (-0.04, 0.98)		
MMRM: P-value	0.068		
Corrected Hedges' g (95% CI)	0.298 (-0.031, 0.626)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.009		
Percent Change in Pain in Left Ribs at Week 24 from Baseline			
n	43	66	
Mean (SD)	-37.9 (60.50)	-45.3 (67.36)	
Median	-44.9	-58.0	
Q1, Q3	-93.8, -6.0	-97.8, -29.9	
Min, Max	-100.0, 175.0	-100.0, 263.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Percent Change from Baseline at Week 24		
n [1]	55	78
n [2]	43	66
MMRM: Least Squares Mean [SE] (95% CI)	-25.80 [10.62] (-46.81, -4.79)	-32.48 [9.07] (-50.43, -14.54)
MMRM: Least Squares Mean Difference [SE] (95% CI)	6.68 [13.30] (-19.64, 33.01)	
MMRM: P-value	0.62	
Corrected Hedges' g (95% CI)	0.092 (-0.292, 0.476)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.24	
TSS Item: Inactivity		
Inactivity at Baseline		
n	85	93
Mean (SD)	3.8 (2.70)	3.7 (2.59)
Median	3.7	3.3
Q1, Q3	1.4, 6.0	1.6, 5.6
Min, Max	0.0, 10.0	0.0, 9.4
Inactivity at Week 4		
n	79	92
Mean (SD)	3.7 (2.55)	3.1 (2.41)
Median	3.0	3.0
Q1, Q3	1.8, 6.0	0.8, 4.7
Min, Max	0.0, 10.0	0.0, 9.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Inactivity at Week 4 from Baseline			
n	78	91	
Mean (SD)	-0.1 (1.22)	-0.6 (1.25)	
Median	-0.2	-0.3	
Q1, Q3	-0.8, 0.3	-1.2, 0.1	
Min, Max	-3.0, 4.4	-3.9, 3.1	
Difference in Change from Baseline at Week 4			
n [1]	80	93	
n [2]	78	91	
MMRM: Least Squares Mean [SE] (95% CI)	-0.16 [0.15] (-0.45, 0.13)	-0.63 [0.14] (-0.90, -0.36)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.47 [0.18] (0.11, 0.83)		
MMRM: P-value	0.011		
Corrected Hedges' g (95% CI)	0.356 (0.051, 0.661)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.20		
Percent Change in Inactivity at Week 4 from Baseline			
n	71	80	
Mean (SD)	6.1 (65.81)	-8.4 (74.86)	
Median	-8.3	-13.2	
Q1, Q3	-28.2, 9.3	-38.7, 8.4	
Min, Max	-75.9, 256.0	-100.0, 500.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Percent Change from Baseline at Week 4		
n [1]	73	82
n [2]	71	80
MMRM: Least Squares Mean [SE] (95% CI)	4.30 [8.77] (-13.03, 21.64)	-9.17 [8.38] (-25.72, 7.39)
MMRM: Least Squares Mean Difference [SE] (95% CI)	13.47 [11.36] (-8.97, 35.91)	
MMRM: P-value	0.24	
Corrected Hedges' g (95% CI)	0.180 (-0.140, 0.500)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.38	
Inactivity at Week 8		
n	76	92
Mean (SD)	3.4 (2.52)	2.8 (2.32)
Median	2.7	2.5
Q1, Q3	1.6, 5.2	0.5, 4.5
Min, Max	0.0, 10.0	0.0, 9.0
Change in Inactivity at Week 8 from Baseline		
n	75	91
Mean (SD)	-0.3 (1.54)	-0.9 (1.99)
Median	-0.1	-0.5
Q1, Q3	-1.3, 0.8	-2.0, 0.4
Min, Max	-3.7, 4.5	-6.7, 3.7

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-tss-item-gba.sas V.03.05 Output file: t-chg-tss-item-gba.pdf 29AUG2023: 9:49

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Change from Baseline at Week 8		
n [1]	80	93
n [2]	75	91
MMRM: Least Squares Mean [SE] (95% CI)	-0.34 [0.20] (-0.73, 0.06)	-0.87 [0.18] (-1.24, -0.51)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.54 [0.26] (0.03, 1.05)	
MMRM: P-value	0.037	
Corrected Hedges' g (95% CI)	0.308 (0.000, 0.615)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.16	
Percent Change in Inactivity at Week 8 from Baseline		
n	68	80
Mean (SD)	1.1 (66.53)	10.5 (256.33)
Median	-10.6	-23.7
Q1, Q3	-39.0, 18.4	-58.8, 16.0
Min, Max	-91.1, 262.5	-100.0, 2214.3
Difference in Percent Change from Baseline at Week 8		
n [1]	73	82
n [2]	68	80
MMRM: Least Squares Mean [SE] (95% CI)	-4.70 [22.91] (-49.99, 40.58)	10.45 [21.33] (-31.70, 52.60)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-15.15 [30.99] (-76.39, 46.08)	
MMRM: P-value	0.63	
Corrected Hedges' g (95% CI)	-0.079 (-0.403, 0.244)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.27	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Inactivity at Week 12			
n	74	90	
Mean (SD)	3.3 (2.41)	2.7 (2.32)	
Median	3.0	2.4	
Q1, Q3	1.1, 5.1	0.5, 3.9	
Min, Max	0.0, 10.0	0.0, 8.0	
Change in Inactivity at Week 12 from Baseline			
n	73	89	
Mean (SD)	-0.4 (1.67)	-0.9 (2.16)	
Median	-0.4	-0.6	
Q1, Q3	-1.4, 0.5	-1.6, 0.2	
Min, Max	-4.2, 4.9	-7.4, 3.7	
Difference in Change from Baseline at Week 12			
n [1]	80	93	
n [2]	73	89	
MMRM: Least Squares Mean [SE] (95% CI)	-0.41 [0.21] (-0.83, 0.01)	-0.88 [0.20] (-1.27, -0.49)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.47 [0.28] (-0.07, 1.02)		
MMRM: P-value	0.090		
Corrected Hedges' g (95% CI)	0.255 (-0.055, 0.566)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.31		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Inactivity at Week 12 from Baseline		
n	66	78
Mean (SD)	-0.9 (90.84)	12.3 (262.14)
Median	-17.1	-24.9
Q1, Q3	-42.6, 15.3	-62.5, 10.4
Min, Max	-100.0, 450.0	-100.0, 2211.1
Difference in Percent Change from Baseline at Week 12		
n [1]	73	82
n [2]	66	78
MMRM: Least Squares Mean [SE] (95% CI)	-6.91 [23.65] (-53.66, 39.83)	12.06 [21.98] (-31.38, 55.51)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-18.97 [31.98] (-82.18, 44.23)	
MMRM: P-value	0.55	
Corrected Hedges' g (95% CI)	-0.098 (-0.426, 0.230)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.22	
Inactivity at Week 16		
n	74	86
Mean (SD)	3.3 (2.42)	2.6 (2.30)
Median	3.1	2.5
Q1, Q3	1.0, 5.0	0.5, 4.2
Min, Max	0.0, 10.0	0.0, 8.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Inactivity at Week 16 from Baseline			
n	73	85	
Mean (SD)	-0.3 (1.75)	-0.8 (2.18)	
Median	-0.1	-0.4	
Q1, Q3	-1.4, 0.5	-1.6, 0.5	
Min, Max	-5.7, 4.4	-7.4, 3.5	
Difference in Change from Baseline at Week 16			
n [1]	80	93	
n [2]	73	85	
MMRM: Least Squares Mean [SE] (95% CI)	-0.39 [0.22] (-0.82, 0.05)	-0.89 [0.20] (-1.30, -0.49)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.51 [0.29] (-0.06, 1.07)		
MMRM: P-value	0.078		
Corrected Hedges' g (95% CI)	0.269 (-0.045, 0.583)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.36		
Percent Change in Inactivity at Week 16 from Baseline			
n	66	74	
Mean (SD)	2.1 (95.52)	16.1 (257.79)	
Median	-18.3	-19.0	
Q1, Q3	-41.7, 21.1	-62.5, 21.2	
Min, Max	-100.0, 475.0	-100.0, 2122.2	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Percent Change from Baseline at Week 16		
n [1]	73	82
n [2]	66	74
MMRM: Least Squares Mean [SE] (95% CI)	-3.77 [22.92] (-49.07, 41.54)	13.17 [21.30] (-28.93, 55.26)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-16.93 [30.98] (-78.15, 44.29)	
MMRM: P-value	0.59	
Corrected Hedges' g (95% CI)	-0.091 (-0.423, 0.241)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.48	
Inactivity at Week 20		
n	72	87
Mean (SD)	3.3 (2.48)	2.7 (2.27)
Median	3.1	2.3
Q1, Q3	1.3, 5.2	0.5, 4.0
Min, Max	0.0, 10.0	0.0, 8.7
Change in Inactivity at Week 20 from Baseline		
n	71	86
Mean (SD)	-0.3 (1.87)	-0.8 (2.18)
Median	-0.3	-0.2
Q1, Q3	-1.4, 0.4	-1.6, 0.4
Min, Max	-6.9, 4.1	-7.4, 3.9

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Change from Baseline at Week 20		
n [1]	80	93
n [2]	71	86
MMRM: Least Squares Mean [SE] (95% CI)	-0.34 [0.23] (-0.79, 0.10)	-0.87 [0.21] (-1.29, -0.46)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.53 [0.30] (-0.05, 1.11)	
MMRM: P-value	0.075	
Corrected Hedges' g (95% CI)	0.274 (-0.042, 0.590)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.35	
Percent Change in Inactivity at Week 20 from Baseline		
n	64	75
Mean (SD)	6.0 (113.78)	25.9 (286.45)
Median	-14.6	-20.9
Q1, Q3	-42.2, 14.0	-61.3, 28.1
Min, Max	-100.0, 675.0	-100.0, 2324.0
Difference in Percent Change from Baseline at Week 20		
n [1]	73	82
n [2]	64	75
MMRM: Least Squares Mean [SE] (95% CI)	0.76 [25.86] (-50.34, 51.87)	22.30 [23.98] (-25.10, 69.70)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-21.53 [34.99] (-90.68, 47.62)	
MMRM: P-value	0.54	
Corrected Hedges' g (95% CI)	-0.103 (-0.437, 0.230)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.47	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Inactivity at Week 24			
n	67	80	
Mean (SD)	2.9 (2.26)	2.6 (2.27)	
Median	2.8	2.2	
Q1, Q3	1.2, 4.5	0.3, 4.1	
Min, Max	0.0, 10.0	0.0, 8.9	
Change in Inactivity at Week 24 from Baseline			
n	66	79	
Mean (SD)	-0.5 (1.88)	-0.9 (2.17)	
Median	-0.2	-0.3	
Q1, Q3	-1.4, 0.5	-1.6, 0.3	
Min, Max	-7.4, 3.7	-7.2, 4.3	
Difference in Change from Baseline at Week 24			
n [1]	80	93	
n [2]	66	79	
MMRM: Least Squares Mean [SE] (95% CI)	-0.49 [0.22] (-0.93, -0.05)	-0.94 [0.21] (-1.34, -0.53)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.45 [0.29] (-0.13, 1.02)		
MMRM: P-value	0.12		
Corrected Hedges' g (95% CI)	0.245 (-0.083, 0.573)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.25		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.1101: Analysis of TSS Items at every 4 weeks and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in Inactivity at Week 24 from Baseline		
n	59	68
Mean (SD)	-3.4 (98.78)	29.7 (328.75)
Median	-18.6	-21.0
Q1, Q3	-46.6, 12.5	-69.5, 10.4
Min, Max	-100.0, 468.8	-100.0, 2575.0
Difference in Percent Change from Baseline at Week 24		
n [1]	73	82
n [2]	59	68
MMRM: Least Squares Mean [SE] (95% CI)	-6.40 [27.67] (-61.08, 48.28)	22.92 [25.64] (-27.76, 73.60)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-29.32 [37.46] (-103.36, 44.72)	
MMRM: P-value	0.44	
Corrected Hedges' g (95% CI)	-0.137 (-0.487, 0.212)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.48	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.0801: Analysis of TSS, Change and % Change from Baseline by Every 4 weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Average Daily Total Symptom Score at Baseline		
n	85	93
Mean (SD)	19.0 (13.72)	18.1 (11.90)
Median	17.6	16.3
Q1, Q3	6.3, 29.3	8.9, 24.9
Min, Max	0.0, 50.4	0.3, 45.2
Average Daily Total Symptom Score at Week 4		
n	79	92
Mean (SD)	16.7 (13.58)	14.6 (11.11)
Median	13.0	12.1
Q1, Q3	5.6, 25.3	6.0, 21.1
Min, Max	0.2, 53.7	0.2, 42.4
Change in Average Daily Total Symptom Score at Week 4 from Baseline		
n	78	91
Mean (SD)	-2.5 (4.92)	-3.4 (4.95)
Median	-1.9	-2.4
Q1, Q3	-5.5, 0.8	-6.0, -0.6
Min, Max	-22.2, 7.5	-22.0, 13.6

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.0801: Analysis of TSS, Change and % Change from Baseline by Every 4 weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	80	93	
n [2]	78	91	
MMRM: Least Squares Mean [SE] (95% CI)	-2.35 [0.60] (-3.54, -1.16)	-3.24 [0.57] (-4.36, -2.11)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.89 [0.75] (-0.60, 2.38)		
MMRM: P-value	0.24		
Corrected Hedges' g (95% CI)	0.165 (-0.138, 0.468)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.16		
Percent Change in Average Daily Total Symptom Score at Week 4 from Baseline			
n	76	91	
Mean (SD)	6.4 (150.59)	-14.8 (77.79)	
Median	-15.9	-19.4	
Q1, Q3	-33.0, 3.9	-38.3, -3.7	
Min, Max	-78.9, 1250.0	-79.3, 668.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	78	93	
n [2]	76	91	
MMRM: Least Squares Mean [SE] (95% CI)	6.19 [13.26] (-19.99, 32.38)	-12.23 [12.20] (-36.32, 11.86)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	18.42 [17.68] (-16.49, 53.34)		
MMRM: P-value	0.30		
Corrected Hedges' g (95% CI)	0.158 (-0.147, 0.463)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.19		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.0801: Analysis of TSS, Change and % Change from Baseline by Every 4 weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Average Daily Total Symptom Score at Week 8			
n	76	92	
Mean (SD)	15.1 (13.44)	12.3 (9.77)	
Median	10.3	10.4	
Q1, Q3	4.8, 20.2	4.1, 16.8	
Min, Max	0.1, 57.7	0.0, 35.5	
Change in Average Daily Total Symptom Score at Week 8 from Baseline			
n	75	91	
Mean (SD)	-4.0 (7.27)	-5.5 (7.23)	
Median	-3.1	-3.6	
Q1, Q3	-9.5, 1.1	-9.0, -0.4	
Min, Max	-24.2, 11.0	-24.4, 12.3	
Difference in Change from Baseline at Week 8			
n [1]	80	93	
n [2]	75	91	
MMRM: Least Squares Mean [SE] (95% CI)	-3.88 [0.81] (-5.47, -2.29)	-5.28 [0.75] (-6.75, -3.80)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.40 [1.04] (-0.66, 3.46)		
MMRM: P-value	0.18		
Corrected Hedges' g (95% CI)	0.198 (-0.109, 0.504)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.21		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.0801: Analysis of TSS, Change and % Change from Baseline by Every 4 weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Average Daily Total Symptom Score at Week 8 from Baseline			
n	73	91	
Mean (SD)	10.3 (238.75)	-15.0 (152.89)	
Median	-22.7	-29.0	
Q1, Q3	-45.9, -2.0	-56.0, -6.8	
Min, Max	-96.7, 1975.0	-100.0, 1376.9	
Difference in Percent Change from Baseline at Week 8			
n [1]	78	93	
n [2]	73	91	
MMRM: Least Squares Mean [SE] (95% CI)	7.12 [21.90] (-36.12, 50.35)	-11.47 [20.06] (-51.09, 28.14)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	18.59 [29.48] (-39.63, 76.81)		
MMRM: P-value	0.53		
Corrected Hedges' g (95% CI)	0.098 (-0.210, 0.406)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.23		
Average Daily Total Symptom Score at Week 12			
n	74	90	
Mean (SD)	14.1 (13.13)	11.8 (9.36)	
Median	10.0	9.5	
Q1, Q3	4.9, 19.3	4.4, 17.6	
Min, Max	0.0, 52.1	0.0, 36.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.0801: Analysis of TSS, Change and % Change from Baseline by Every 4 weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Average Daily Total Symptom Score at Week 12 from Baseline			
n	73	89	
Mean (SD)	-4.6 (7.85)	-5.7 (7.55)	
Median	-3.7	-4.3	
Q1, Q3	-10.9, 0.0	-9.5, -0.1	
Min, Max	-25.1, 11.0	-25.7, 16.1	
Difference in Change from Baseline at Week 12			
n [1]	80	93	
n [2]	73	89	
MMRM: Least Squares Mean [SE] (95% CI)	-4.50 [0.86] (-6.18, -2.81)	-5.56 [0.79] (-7.11, -4.00)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.06 [1.11] (-1.13, 3.25)		
MMRM: P-value	0.34		
Corrected Hedges' g (95% CI)	0.143 (-0.167, 0.453)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.50		
Percent Change in Average Daily Total Symptom Score at Week 12 from Baseline			
n	71	89	
Mean (SD)	12.4 (234.38)	-13.4 (148.58)	
Median	-34.4	-35.0	
Q1, Q3	-55.3, -0.6	-60.1, -1.1	
Min, Max	-100.0, 1792.6	-100.0, 1232.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.0801: Analysis of TSS, Change and % Change from Baseline by Every 4 weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	78	93	
n [2]	71	89	
MMRM: Least Squares Mean [SE] (95% CI)	8.84 [21.29] (-33.20, 50.87)		-9.97 [19.47] (-48.41, 28.47)
MMRM: Least Squares Mean Difference [SE] (95% CI)	18.80 [28.63] (-37.73, 75.33)		
MMRM: P-value	0.51		
Corrected Hedges' g (95% CI)	0.103 (-0.209, 0.415)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.47		
Average Daily Total Symptom Score at Week 16			
n	74	86	
Mean (SD)	14.1 (13.61)	11.1 (9.11)	
Median	11.3	9.6	
Q1, Q3	4.0, 18.4	3.8, 15.7	
Min, Max	0.0, 60.4	0.0, 36.8	
Change in Average Daily Total Symptom Score at Week 16 from Baseline			
n	73	85	
Mean (SD)	-4.6 (8.40)	-6.2 (8.31)	
Median	-3.3	-4.4	
Q1, Q3	-10.0, 1.4	-11.9, -0.2	
Min, Max	-34.6, 13.2	-29.1, 18.4	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.0801: Analysis of TSS, Change and % Change from Baseline by Every 4 weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	80	93	
n [2]	73	85	
MMRM: Least Squares Mean [SE] (95% CI)	-4.52 [0.93] (-6.36, -2.69)	-6.01 [0.85] (-7.70, -4.32)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.49 [1.21] (-0.91, 3.88)		
MMRM: P-value	0.22		
Corrected Hedges' g (95% CI)	0.187 (-0.126, 0.501)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.20		
Percent Change in Average Daily Total Symptom Score at Week 16 from Baseline			
n	71	85	
Mean (SD)	15.8 (253.18)	-27.9 (60.04)	
Median	-31.3	-36.8	
Q1, Q3	-52.1, 8.2	-64.3, -2.7	
Min, Max	-100.0, 1974.1	-99.7, 322.2	
Difference in Percent Change from Baseline at Week 16			
n [1]	78	93	
n [2]	71	85	
MMRM: Least Squares Mean [SE] (95% CI)	12.70 [19.53] (-25.86, 51.26)	-26.54 [17.85] (-61.79, 8.70)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	39.24 [26.22] (-12.53, 91.02)		
MMRM: P-value	0.14		
Corrected Hedges' g (95% CI)	0.237 (-0.079, 0.554)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.25		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.0801: Analysis of TSS, Change and % Change from Baseline by Every 4 weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Average Daily Total Symptom Score at Week 20			
n	72	87	
Mean (SD)	14.0 (14.28)	11.0 (8.77)	
Median	10.9	9.6	
Q1, Q3	3.8, 18.3	4.1, 17.5	
Min, Max	0.0, 64.4	0.0, 40.3	
Change in Average Daily Total Symptom Score at Week 20 from Baseline			
n	71	86	
Mean (SD)	-4.8 (8.62)	-6.3 (8.20)	
Median	-3.4	-3.9	
Q1, Q3	-9.7, 0.3	-10.8, -0.9	
Min, Max	-38.8, 14.9	-29.9, 15.9	
Difference in Change from Baseline at Week 20			
n [1]	80	93	
n [2]	71	86	
MMRM: Least Squares Mean [SE] (95% CI)	-4.38 [0.94] (-6.23, -2.52)	-6.14 [0.86] (-7.84, -4.43)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.76 [1.23] (-0.67, 4.19)		
MMRM: P-value	0.15		
Corrected Hedges' g (95% CI)	0.220 (-0.095, 0.535)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.37		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.0801: Analysis of TSS, Change and % Change from Baseline by Every 4 weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Average Daily Total Symptom Score at Week 20 from Baseline			
n	69	86	
Mean (SD)	22.6 (326.63)	-27.9 (53.08)	
Median	-30.2	-36.8	
Q1, Q3	-56.1, -2.4	-65.8, -7.5	
Min, Max	-100.0, 2600.0	-100.0, 216.7	
Difference in Percent Change from Baseline at Week 20			
n [1]	78	93	
n [2]	69	86	
MMRM: Least Squares Mean [SE] (95% CI)	18.89 [24.46] (-29.42, 67.19)	-27.35 [22.33] (-71.44, 16.74)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	46.24 [32.93] (-18.78, 111.26)		
MMRM: P-value	0.16		
Corrected Hedges' g (95% CI)	0.224 (-0.094, 0.542)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.31		
Average Daily Total Symptom Score at Week 24			
n	67	80	
Mean (SD)	12.0 (12.51)	10.1 (8.32)	
Median	7.6	8.6	
Q1, Q3	3.9, 16.7	3.2, 13.4	
Min, Max	0.0, 64.5	0.0, 37.7	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.0801: Analysis of TSS, Change and % Change from Baseline by Every 4 weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Average Daily Total Symptom Score at Week 24 from Baseline			
n	66	79	
Mean (SD)	-4.7 (8.82)	-6.5 (8.10)	
Median	-3.3	-4.5	
Q1, Q3	-10.0, 0.6	-10.8, -1.1	
Min, Max	-39.5, 15.0	-27.6, 11.5	
Difference in Change from Baseline at Week 24			
n [1]	80	93	
n [2]	66	79	
MMRM: Least Squares Mean [SE] (95% CI)	-4.37 [0.95] (-6.24, -2.49)		-6.44 [0.87] (-8.16, -4.72)
MMRM: Least Squares Mean Difference [SE] (95% CI)	2.07 [1.24] (-0.39, 4.52)		
MMRM: P-value	0.098		
Corrected Hedges' g (95% CI)	0.266 (-0.062, 0.594)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.46		
Percent Change in Average Daily Total Symptom Score at Week 24 from Baseline			
n	64	79	
Mean (SD)	33.8 (434.68)	-33.2 (50.83)	
Median	-29.3	-40.1	
Q1, Q3	-61.9, 5.1	-70.6, -8.9	
Min, Max	-100.0, 3400.0	-100.0, 246.2	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.0801: Analysis of TSS, Change and % Change from Baseline by Every 4 weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	78	93	
n [2]	64	79	
MMRM: Least Squares Mean [SE] (95% CI)	24.11 [31.10] (-37.31, 85.53)		-32.64 [28.39] (-88.69, 23.42)
MMRM: Least Squares Mean Difference [SE] (95% CI)	56.75 [41.95] (-26.09, 139.58)		
MMRM: P-value	0.18		
Corrected Hedges' g (95% CI)	0.225 (-0.106, 0.556)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.22		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.0736: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Inactivity) by Every 4 Weeks

Double-Blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Inactivity Symptom Score Status			
Missing Inactivity Score at baseline (excluded from rate calculation)	1 (1.2%)	1 (1.1%)	2 (1.1%)
Inactivity Score = 0 at baseline	8 (9.3%)	11 (11.7%)	19 (10.6%)
Inactivity Score > 0 at baseline	77 (89.5%)	82 (87.2%)	159 (88.3%)
Response Rate of Inactivity Symptom Score at Week 4			
Subjects Evaluable at Week 4, n	84	85	169
Inactivity Score = 0 at baseline and Inactivity Score >0 or missing at Week 4	7 (8.3%)	3 (3.5%)	10 (5.9%)
Responder, n(%)	7 (8.3%)	16 (18.8%)	23 (13.6%)
95% Exact CI	0.0342, 0.1642	0.1116, 0.2876	0.0883, 0.1972
Proportion Difference - Stratified CMH Method (95% CI)		-0.11 (-0.23, 0.00)	
p-value	0.049		
Proportion Difference - Unstratified CMH Method (95% CI)		-0.10 (-0.21, 0.00)	
p-value	0.048		
Proportion Difference - Unstratified Exact Method (95% CI)		-0.10 (-0.25, 0.04)	
p-value	0.071		
Unadjusted Inverse Relative Risk (95% CI)		2.26 (0.98, 5.21)	
p-value [1]	0.056		
Unadjusted Inverse Odds Ratio (95% CI)		2.55 (0.99, 6.57)	
p-value [1]	0.052		
Unadjusted Absolute Risk Difference (95% CI)		-0.10 (-0.21, 0.00)	
Adjusted Inverse Relative Risk (95% CI) [2]		2.42 (1.03, 5.68)	
p-value [2]	0.043		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

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Table 2.0736: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Inactivity) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	77 (91.7%)	69 (81.2%)	146 (86.4%)
Last participation date < Day 21 in DB Phase	4 (4.8%)	0	4 (2.4%)
Last participation date >= Day 21 and Inactivity Score at Week 4 not available	4 (4.8%)	2 (2.4%)	6 (3.6%)
>0% increase from baseline at Week 4	24 (28.6%)	25 (29.4%)	49 (29.0%)
<50% reduction from baseline at Week 4	63 (75.0%)	64 (75.3%)	127 (75.1%)
Return Rate (%)	91%	98%	94%
Number of Subjects in Risk	82	94	176
Return Rate in Risk (%)	95%	98%	97%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0736: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Inactivity) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Inactivity Symptom Score at Week 8			
Subjects Evaluable at Week 8, n	84	85	169
Inactivity Score = 0 at baseline and Inactivity Score >0 or missing at Week 8	7 (8.3%)	3 (3.5%)	10 (5.9%)
Responder, n(%)	8 (9.5%)	22 (25.9%)	30 (17.8%)
95% Exact CI	0.0420, 0.1791	0.1699, 0.3652	0.1231, 0.2436
Proportion Difference - Stratified CMH Method (95% CI)		-0.17 (-0.29, -0.05)	
p-value		0.007	
Proportion Difference - Unstratified CMH Method (95% CI)		-0.16 (-0.28, -0.05)	
p-value		0.005	
Proportion Difference - Unstratified Exact Method (95% CI)		-0.16 (-0.31, -0.02)	
p-value		0.008	
Unadjusted Inverse Relative Risk (95% CI)		2.72 (1.28, 5.76)	
p-value [1]		0.009	
Unadjusted Inverse Odds Ratio (95% CI)		3.32 (1.38, 7.96)	
p-value [1]		0.007	
Unadjusted Absolute Risk Difference (95% CI)		-0.16 (-0.28, -0.05)	
Adjusted Inverse Relative Risk (95% CI) [2]		2.82 (1.29, 6.14)	
p-value [2]		0.009	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0736: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Inactivity) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	76 (90.5%)	63 (74.1%)	139 (82.2%)
Last participation date < Day 50 in DB Phase	7 (8.3%)	0	7 (4.1%)
Last participation date >= Day 50 and Inactivity Score at Week 8 not available	3 (3.6%)	2 (2.4%)	5 (3.0%)
>0% increase from baseline at Week 8	26 (31.0%)	25 (29.4%)	51 (30.2%)
<50% reduction from baseline at Week 8	60 (71.4%)	58 (68.2%)	118 (69.8%)
Return Rate (%)	88%	98%	93%
Number of Subjects in Risk	79	94	173
Return Rate in Risk (%)	96%	98%	97%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0736: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Inactivity) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Inactivity Symptom Score at Week 12			
Subjects Evaluable at Week 12, n	82	84	166
Inactivity Score = 0 at baseline and Inactivity Score >0 or missing at Week 12	5 (6.1%)	2 (2.4%)	7 (4.2%)
Responder, n(%)	14 (17.1%)	22 (26.2%)	36 (21.7%)
95% Exact CI	0.0966, 0.2698	0.1720, 0.3693	0.1568, 0.2874
Proportion Difference - Stratified CMH Method (95% CI)	-0.10 (-0.23, 0.03)		
p-value	0.12		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.09 (-0.22, 0.03)		
p-value	0.16		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.09 (-0.24, 0.06)		
p-value	0.19		
Unadjusted Inverse Relative Risk (95% CI)	1.53 (0.84, 2.79)		
p-value [1]	0.16		
Unadjusted Inverse Odds Ratio (95% CI)	1.72 (0.81, 3.66)		
p-value [1]	0.16		
Unadjusted Absolute Risk Difference (95% CI)	-0.09 (-0.22, 0.03)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.62 (0.90, 2.94)		
p-value [2]	0.11		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0736: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Inactivity) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	68 (82.9%)	62 (73.8%)	130 (78.3%)
Last participation date < Day 78 in DB Phase	10 (12.2%)	0	10 (6.0%)
Last participation date >= Day 78 and Inactivity Score at Week 12 not available	2 (2.4%)	4 (4.8%)	6 (3.6%)
>0% increase from baseline at Week 12	22 (26.8%)	23 (27.4%)	45 (27.1%)
<50% reduction from baseline at Week 12	52 (63.4%)	56 (66.7%)	108 (65.1%)
Return Rate (%)	86%	96%	91%
Number of Subjects in Risk	76	94	170
Return Rate in Risk (%)	97%	96%	96%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0736: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Inactivity) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Inactivity Symptom Score at Week 16			
Subjects Evaluable at Week 16, n	83	86	169
Inactivity Score = 0 at baseline and Inactivity Score >0 or missing at Week 16	6 (7.2%)	4 (4.7%)	10 (5.9%)
Responder, n(%)	13 (15.7%)	22 (25.6%)	35 (20.7%)
95% Exact CI	0.0861, 0.2529	0.1678, 0.3613	0.1487, 0.2761
Proportion Difference - Stratified CMH Method (95% CI)	-0.11 (-0.24, 0.02)		
p-value	0.089		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.10 (-0.22, 0.02)		
p-value	0.11		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.10 (-0.25, 0.05)		
p-value	0.13		
Unadjusted Inverse Relative Risk (95% CI)	1.63 (0.88, 3.02)		
p-value [1]	0.12		
Unadjusted Inverse Odds Ratio (95% CI)	1.85 (0.86, 3.98)		
p-value [1]	0.11		
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.22, 0.02)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.72 (0.95, 3.11)		
p-value [2]	0.074		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0736: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Inactivity) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	70 (84.3%)	64 (74.4%)	134 (79.3%)
Last participation date < Day 106 in DB Phase	11 (13.3%)	4 (4.7%)	15 (8.9%)
Last participation date >= Day 106 and Inactivity Score at Week 16 not available	2 (2.4%)	4 (4.7%)	6 (3.6%)
>0% increase from baseline at Week 16	25 (30.1%)	28 (32.6%)	53 (31.4%)
<50% reduction from baseline at Week 16	52 (62.7%)	52 (60.5%)	104 (61.5%)
Return Rate (%)	85%	91%	88%
Number of Subjects in Risk	75	90	165
Return Rate in Risk (%)	97%	96%	96%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0736: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Inactivity) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Inactivity Symptom Score at Week 20			
Subjects Evaluable at Week 20, n	80	85	165
Inactivity Score = 0 at baseline and Inactivity Score >0 or missing at Week 20	3 (3.8%)	3 (3.5%)	6 (3.6%)
Responder, n(%)	9 (11.3%)	19 (22.4%)	28 (17.0%)
95% Exact CI	0.0528, 0.2028	0.1403, 0.3269	0.1158, 0.2358
Proportion Difference - Stratified CMH Method (95% CI)		-0.12 (-0.24, 0.01)	
p-value		0.063	
Proportion Difference - Unstratified CMH Method (95% CI)		-0.11 (-0.23, 0.00)	
p-value		0.057	
Proportion Difference - Unstratified Exact Method (95% CI)		-0.11 (-0.26, 0.04)	
p-value		0.065	
Unadjusted Inverse Relative Risk (95% CI)		1.99 (0.96, 4.13)	
p-value [1]		0.066	
Unadjusted Inverse Odds Ratio (95% CI)		2.27 (0.96, 5.37)	
p-value [1]		0.062	
Unadjusted Absolute Risk Difference (95% CI)		-0.11 (-0.22, 0.00)	
Adjusted Inverse Relative Risk (95% CI) [2]		2.06 (0.97, 4.37)	
p-value [2]		0.060	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0736: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Inactivity) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	71 (88.8%)	66 (77.6%)	137 (83.0%)
Last participation date < Day 134 in DB Phase	12 (15.0%)	4 (4.7%)	16 (9.7%)
Last participation date >= Day 134 and Inactivity Score at Week 20 not available	3 (3.8%)	3 (3.5%)	6 (3.6%)
>0% increase from baseline at Week 20	25 (31.3%)	30 (35.3%)	55 (33.3%)
<50% reduction from baseline at Week 20	54 (67.5%)	56 (65.9%)	110 (66.7%)
Return Rate (%)	83%	93%	88%
Number of Subjects in Risk	74	90	164
Return Rate in Risk (%)	96%	97%	96%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0736: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Inactivity) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Inactivity Symptom Score at Week 24			
Subjects Evaluable at Week 24, n	83	84	167
Inactivity Score = 0 at baseline and Inactivity Score >0 or missing at Week 24	6 (7.2%)	2 (2.4%)	8 (4.8%)
Responder, n(%)	13 (15.7%)	22 (26.2%)	35 (21.0%)
95% Exact CI	0.0861, 0.2529	0.1720, 0.3693	0.1505, 0.2792
Proportion Difference - Stratified CMH Method (95% CI)	-0.11 (-0.24, 0.02)		
p-value	0.095		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.11 (-0.23, 0.02)		
p-value	0.096		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.11 (-0.26, 0.04)		
p-value	0.13		
Unadjusted Inverse Relative Risk (95% CI)	1.67 (0.90, 3.09)		
p-value [1]	0.10		
Unadjusted Inverse Odds Ratio (95% CI)	1.91 (0.89, 4.11)		
p-value [1]	0.098		
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.23, 0.02)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.72 (0.92, 3.22)		
p-value [2]	0.087		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0736: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Inactivity) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	70 (84.3%)	62 (73.8%)	132 (79.0%)
Last participation date < Day 162 in DB Phase	16 (19.3%)	8 (9.5%)	24 (14.4%)
Last participation date >= Day 162 and Inactivity Score at Week 24 not available	3 (3.6%)	6 (7.1%)	9 (5.4%)
>0% increase from baseline at Week 24	19 (22.9%)	22 (26.2%)	41 (24.6%)
<50% reduction from baseline at Week 24	46 (55.4%)	46 (54.8%)	92 (55.1%)
Return Rate (%)	78%	85%	82%
Number of Subjects in Risk	70	86	156
Return Rate in Risk (%)	96%	93%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019
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GSK Oncology

Study GS-US-352-0101

Table 2.0735: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Pain L Ribs) by Every 4 Weeks

Double-Blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Pain L Ribs Symptom Score Status			
Missing Pain L Ribs Score at baseline (excluded from rate calculation)	1 (1.2%)	1 (1.1%)	2 (1.1%)
Pain L Ribs Score = 0 at baseline	27 (31.4%)	15 (16.0%)	42 (23.3%)
Pain L Ribs Score > 0 at baseline	58 (67.4%)	78 (83.0%)	136 (75.6%)
Response Rate of Pain L Ribs Symptom Score at Week 4			
Subjects Evaluable at Week 4, n	65	88	153
Pain L Ribs Score = 0 at baseline and Pain L Ribs Score >0 or missing at Week 4	7 (10.8%)	10 (11.4%)	17 (11.1%)
Responder, n(%)	9 (13.8%)	20 (22.7%)	29 (19.0%)
95% Exact CI	0.0653, 0.2466	0.1447, 0.3289	0.1308, 0.2607
Proportion Difference - Stratified CMH Method (95% CI)		-0.09 (-0.22, 0.04)	
p-value		0.17	
Proportion Difference - Unstratified CMH Method (95% CI)		-0.09 (-0.21, 0.03)	
p-value		0.16	
Proportion Difference - Unstratified Exact Method (95% CI)		-0.09 (-0.25, 0.07)	
p-value		0.21	
Unadjusted Inverse Relative Risk (95% CI)		1.64 (0.80, 3.37)	
p-value [1]		0.18	
Unadjusted Inverse Odds Ratio (95% CI)		1.83 (0.77, 4.34)	
p-value [1]		0.17	
Unadjusted Absolute Risk Difference (95% CI)		-0.09 (-0.21, 0.03)	
Adjusted Inverse Relative Risk (95% CI) [2]		NE	
p-value [2]		NE	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

GSK Oncology

Study GS-US-352-0101

Table 2.0735: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Pain L Ribs) by Every 4 Weeks

Double-Blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	56 (86.2%)	68 (77.3%)	124 (81.0%)
Last participation date < Day 21 in DB Phase	4 (6.2%)	0	4 (2.6%)
Last participation date >= Day 21 and Pain L Ribs Score at Week 4 not available	4 (6.2%)	2 (2.3%)	6 (3.9%)
>0% increase from baseline at Week 4	15 (23.1%)	21 (23.9%)	36 (23.5%)
<50% reduction from baseline at Week 4	44 (67.7%)	57 (64.8%)	101 (66.0%)
Return Rate (%)	91%	98%	94%
Number of Subjects in Risk	82	94	176
Return Rate in Risk (%)	95%	98%	97%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

GSK Oncology
Study GS-US-352-0101

Table 2.0735: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Pain L Ribs) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Pain L Ribs Symptom Score at Week 8			
Subjects Evaluable at Week 8, n	70	85	155
Pain L Ribs Score = 0 at baseline and Pain L Ribs Score >0 or missing at Week 8	12 (17.1%)	7 (8.2%)	19 (12.3%)
Responder, n(%)	18 (25.7%)	32 (37.6%)	50 (32.3%)
95% Exact CI	0.1601, 0.3756	0.2736, 0.4882	0.2498, 0.4023
Proportion Difference - Stratified CMH Method (95% CI)	-0.14 (-0.29, 0.01)		
p-value	0.076		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.12 (-0.27, 0.03)		
p-value	0.11		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.12 (-0.27, 0.04)		
p-value	0.12		
Unadjusted Inverse Relative Risk (95% CI)	1.46 (0.90, 2.37)		
p-value [1]	0.12		
Unadjusted Inverse Odds Ratio (95% CI)	1.74 (0.87, 3.49)		
p-value [1]	0.12		
Unadjusted Absolute Risk Difference (95% CI)	-0.12 (-0.26, 0.03)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.55 (0.96, 2.50)		
p-value [2]	0.074		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 01JUL2019
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GSK Oncology
Study GS-US-352-0101

Table 2.0735: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Pain L Ribs) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	52 (74.3%)	53 (62.4%)	105 (67.7%)
Last participation date < Day 50 in DB Phase	7 (10.0%)	0	7 (4.5%)
Last participation date >= Day 50 and Pain L Ribs Score at Week 8 not available	3 (4.3%)	2 (2.4%)	5 (3.2%)
>0% increase from baseline at Week 8	6 (8.6%)	15 (17.6%)	21 (13.5%)
<50% reduction from baseline at Week 8	34 (48.6%)	44 (51.8%)	78 (50.3%)
Return Rate (%)	88%	98%	93%
Number of Subjects in Risk	79	94	173
Return Rate in Risk (%)	96%	98%	97%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 01JUL2019

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Table 2.0735: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Pain L Ribs) by Every 4 Weeks

Double-Blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Pain L Ribs Symptom Score at Week 12			
Subjects Evaluable at Week 12, n	73	85	158
Pain L Ribs Score = 0 at baseline and Pain L Ribs Score >0 or missing at Week 12	15 (20.5%)	7 (8.2%)	22 (13.9%)
Responder, n(%)	21 (28.8%)	35 (41.2%)	56 (35.4%)
95% Exact CI	0.1877, 0.4055	0.3061, 0.5238	0.2801, 0.4344
Proportion Difference - Stratified CMH Method (95% CI)	-0.13 (-0.29, 0.02)		
p-value	0.095		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.12 (-0.27, 0.02)		
p-value	0.10		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.12 (-0.28, 0.03)		
p-value	0.13		
Unadjusted Inverse Relative Risk (95% CI)	1.43 (0.92, 2.23)		
p-value [1]	0.11		
Unadjusted Inverse Odds Ratio (95% CI)	1.73 (0.89, 3.37)		
p-value [1]	0.11		
Unadjusted Absolute Risk Difference (95% CI)	-0.12 (-0.27, 0.02)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.46 (0.94, 2.27)		
p-value [2]	0.090		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

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Table 2.0735: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Pain L Ribs) by Every 4 Weeks

Double-Blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	52 (71.2%)	50 (58.8%)	102 (64.6%)
Last participation date < Day 78 in DB Phase	10 (13.7%)	0	10 (6.3%)
Last participation date >= Day 78 and Pain L Ribs Score at Week 12 not available	2 (2.7%)	4 (4.7%)	6 (3.8%)
>0% increase from baseline at Week 12	13 (17.8%)	12 (14.1%)	25 (15.8%)
<50% reduction from baseline at Week 12	29 (39.7%)	39 (45.9%)	68 (43.0%)
Return Rate (%)	86%	96%	91%
Number of Subjects in Risk	76	94	170
Return Rate in Risk (%)	97%	96%	96%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

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GSK Oncology

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Table 2.0735: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Pain L Ribs) by Every 4 Weeks

Double-Blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Pain L Ribs Symptom Score at Week 16			
Subjects Evaluable at Week 16, n	70	83	153
Pain L Ribs Score = 0 at baseline and Pain L Ribs Score >0 or missing at Week 16	12 (17.1%)	5 (6.0%)	17 (11.1%)
Responder, n(%)	21 (30.0%)	32 (38.6%)	53 (34.6%)
95% Exact CI	0.1962, 0.4213	0.2807, 0.4988	0.2714, 0.4275
Proportion Difference - Stratified CMH Method (95% CI)	-0.09 (-0.25, 0.06)		
p-value	0.25		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.09 (-0.24, 0.07)		
p-value	0.27		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.09 (-0.24, 0.07)		
p-value	0.31		
Unadjusted Inverse Relative Risk (95% CI)	1.29 (0.82, 2.01)		
p-value [1]	0.27		
Unadjusted Inverse Odds Ratio (95% CI)	1.46 (0.74, 2.88)		
p-value [1]	0.27		
Unadjusted Absolute Risk Difference (95% CI)	-0.09 (-0.24, 0.06)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.31 (0.84, 2.05)		
p-value [2]	0.24		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

GSK Oncology
Study GS-US-352-0101

Table 2.0735: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Pain L Ribs) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	49 (70.0%)	51 (61.4%)	100 (65.4%)
Last participation date < Day 106 in DB Phase	10 (14.3%)	4 (4.8%)	14 (9.2%)
Last participation date >= Day 106 and Pain L Ribs Score at Week 16 not available	2 (2.9%)	4 (4.8%)	6 (3.9%)
>0% increase from baseline at Week 16	10 (14.3%)	14 (16.9%)	24 (15.7%)
<50% reduction from baseline at Week 16	29 (41.4%)	39 (47.0%)	68 (44.4%)
Return Rate (%)	86%	91%	89%
Number of Subjects in Risk	76	90	166
Return Rate in Risk (%)	97%	96%	96%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 01JUL2019
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GSK Oncology

Study GS-US-352-0101

Table 2.0735: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Pain L Ribs) by Every 4 Weeks

Double-Blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Pain L Ribs Symptom Score at Week 20			
Subjects Evaluable at Week 20, n	64	84	148
Pain L Ribs Score = 0 at baseline and Pain L Ribs Score >0 or missing at Week 20	6 (9.4%)	6 (7.1%)	12 (8.1%)
Responder, n(%)	23 (35.9%)	36 (42.9%)	59 (39.9%)
95% Exact CI	0.2432, 0.4890	0.3211, 0.5412	0.3192, 0.4823
Proportion Difference - Stratified CMH Method (95% CI)	-0.07 (-0.24, 0.10)		
p-value	0.41		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.07 (-0.23, 0.09)		
p-value	0.39		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.07 (-0.23, 0.09)		
p-value	0.40		
Unadjusted Inverse Relative Risk (95% CI)	1.19 (0.79, 1.80)		
p-value [1]	0.40		
Unadjusted Inverse Odds Ratio (95% CI)	1.34 (0.68, 2.61)		
p-value [1]	0.39		
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.23, 0.09)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.20 (0.79, 1.80)		
p-value [2]	0.39		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.0735: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Pain L Ribs) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	41 (64.1%)	48 (57.1%)	89 (60.1%)
Last participation date < Day 134 in DB Phase	11 (17.2%)	4 (4.8%)	15 (10.1%)
Last participation date >= Day 134 and Pain L Ribs Score at Week 20 not available	3 (4.7%)	3 (3.6%)	6 (4.1%)
>0% increase from baseline at Week 20	8 (12.5%)	11 (13.1%)	19 (12.8%)
<50% reduction from baseline at Week 20	25 (39.1%)	36 (42.9%)	61 (41.2%)
Return Rate (%)	84%	93%	88%
Number of Subjects in Risk	75	90	165
Return Rate in Risk (%)	96%	97%	96%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 01JUL2019

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Table 2.0735: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Pain L Ribs) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Pain L Ribs Symptom Score at Week 24			
Subjects Evaluable at Week 24, n	71	85	156
Pain L Ribs Score = 0 at baseline and Pain L Ribs Score >0 or missing at Week 24	13 (18.3%)	7 (8.2%)	20 (12.8%)
Responder, n(%)	21 (29.6%)	39 (45.9%)	60 (38.5%)
95% Exact CI	0.1933, 0.4159	0.3502, 0.5704	0.3079, 0.4658
Proportion Difference - Stratified CMH Method (95% CI)	-0.17 (-0.33, -0.01)		
p-value	0.032		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.16 (-0.31, -0.01)		
p-value	0.035		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.16 (-0.31, 0.00)		
p-value	0.047		
Unadjusted Inverse Relative Risk (95% CI)	1.55 (1.01, 2.38)		
p-value [1]	0.044		
Unadjusted Inverse Odds Ratio (95% CI)	2.02 (1.04, 3.92)		
p-value [1]	0.038		
Unadjusted Absolute Risk Difference (95% CI)	-0.16 (-0.31, -0.01)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.58 (1.04, 2.42)		
p-value [2]	0.034		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
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GSK Oncology
Study GS-US-352-0101

Table 2.0735: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Pain L Ribs) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	50 (70.4%)	46 (54.1%)	96 (61.5%)
Last participation date < Day 162 in DB Phase	16 (22.5%)	8 (9.4%)	24 (15.4%)
Last participation date >= Day 162 and Pain L Ribs Score at Week 24 not available	3 (4.2%)	6 (7.1%)	9 (5.8%)
>0% increase from baseline at Week 24	8 (11.3%)	8 (9.4%)	16 (10.3%)
<50% reduction from baseline at Week 24	22 (31.0%)	27 (31.8%)	49 (31.4%)
Return Rate (%)	78%	85%	82%
Number of Subjects in Risk	70	86	156
Return Rate in Risk (%)	96%	93%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 01JUL2019
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GSK Oncology

Study GS-US-352-0101

Table 2.0734: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Bone Pain) by Every 4 Weeks

Double-Blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Bone Pain Symptom Score Status			
Missing Bone Pain Score at baseline (excluded from rate calculation)	1 (1.2%)	1 (1.1%)	2 (1.1%)
Bone Pain Score = 0 at baseline	22 (25.6%)	28 (29.8%)	50 (27.8%)
Bone Pain Score > 0 at baseline	63 (73.3%)	65 (69.1%)	128 (71.1%)
Response Rate of Bone Pain Symptom Score at Week 4			
Subjects Evaluable at Week 4, n	72	74	146
Bone Pain Score = 0 at baseline and Bone Pain Score >0 or missing at Week 4	9 (12.5%)	9 (12.2%)	18 (12.3%)
Responder, n(%)	11 (15.3%)	15 (20.3%)	26 (17.8%)
95% Exact CI	0.0788, 0.2569	0.1181, 0.3122	0.1198, 0.2499
Proportion Difference - Stratified CMH Method (95% CI)	-0.06 (-0.19, 0.08)		
p-value	0.40		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.05 (-0.18, 0.08)		
p-value	0.44		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.05 (-0.21, 0.11)		
p-value	0.52		
Unadjusted Inverse Relative Risk (95% CI)	1.33 (0.65, 2.69)		
p-value [1]	0.43		
Unadjusted Inverse Odds Ratio (95% CI)	1.41 (0.60, 3.32)		
p-value [1]	0.43		
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.17, 0.07)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.37 (0.69, 2.72)		
p-value [2]	0.36		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

GSK Oncology
Study GS-US-352-0101
Table 2.0734: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Bone Pain) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	61 (84.7%)	59 (79.7%)	120 (82.2%)
Last participation date < Day 21 in DB Phase	4 (5.6%)	0	4 (2.7%)
Last participation date >= Day 21 and Bone Pain Score at Week 4 not available	4 (5.6%)	2 (2.7%)	6 (4.1%)
>0% increase from baseline at Week 4	18 (25.0%)	24 (32.4%)	42 (28.8%)
<50% reduction from baseline at Week 4	47 (65.3%)	49 (66.2%)	96 (65.8%)
Return Rate (%)	91%	98%	94%
Number of Subjects in Risk	82	94	176
Return Rate in Risk (%)	95%	98%	97%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

GSK Oncology
Study GS-US-352-0101

Table 2.0734: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Bone Pain) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Bone Pain Symptom Score at Week 8			
Subjects Evaluable at Week 8, n	72	74	146
Bone Pain Score = 0 at baseline and Bone Pain Score >0 or missing at Week 8	9 (12.5%)	9 (12.2%)	18 (12.3%)
Responder, n(%)	17 (23.6%)	19 (25.7%)	36 (24.7%)
95% Exact CI	0.1440, 0.3509	0.1622, 0.3716	0.1791, 0.3247
Proportion Difference - Stratified CMH Method (95% CI)	-0.02 (-0.16, 0.13)		
p-value	0.84		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.02 (-0.16, 0.12)		
p-value	0.77		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.02 (-0.18, 0.14)		
p-value	0.85		
Unadjusted Inverse Relative Risk (95% CI)	1.09 (0.62, 1.92)		
p-value [1]	0.77		
Unadjusted Inverse Odds Ratio (95% CI)	1.12 (0.53, 2.37)		
p-value [1]	0.77		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.16, 0.12)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.06 (0.61, 1.86)		
p-value [2]	0.83		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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GSK Oncology
Study GS-US-352-0101
Table 2.0734: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Bone Pain) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	55 (76.4%)	55 (74.3%)	110 (75.3%)
Last participation date < Day 50 in DB Phase	7 (9.7%)	0	7 (4.8%)
Last participation date >= Day 50 and Bone Pain Score at Week 8 not available	3 (4.2%)	2 (2.7%)	5 (3.4%)
>0% increase from baseline at Week 8	17 (23.6%)	18 (24.3%)	35 (24.0%)
<50% reduction from baseline at Week 8	41 (56.9%)	44 (59.5%)	85 (58.2%)
Return Rate (%)	88%	98%	93%
Number of Subjects in Risk	79	94	173
Return Rate in Risk (%)	96%	98%	97%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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GSK Oncology
Study GS-US-352-0101
Table 2.0734: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Bone Pain) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Bone Pain Symptom Score at Week 12			
Subjects Evaluable at Week 12, n	73	72	145
Bone Pain Score = 0 at baseline and Bone Pain Score >0 or missing at Week 12	10 (13.7%)	7 (9.7%)	17 (11.7%)
Responder, n(%)	17 (23.3%)	16 (22.2%)	33 (22.8%)
95% Exact CI	0.1419, 0.3465	0.1327, 0.3356	0.1621, 0.3045
Proportion Difference - Stratified CMH Method (95% CI)	0.01 (-0.13, 0.16)		
p-value	0.86		
Proportion Difference - Unstratified CMH Method (95% CI)	0.01 (-0.13, 0.15)		
p-value	0.88		
Proportion Difference - Unstratified Exact Method (95% CI)	0.01 (-0.15, 0.18)		
p-value	1.00		
Unadjusted Inverse Relative Risk (95% CI)	0.95 (0.52, 1.74)		
p-value [1]	0.88		
Unadjusted Inverse Odds Ratio (95% CI)	0.94 (0.43, 2.05)		
p-value [1]	0.88		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.13, 0.15)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.94 (0.52, 1.70)		
p-value [2]	0.85		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0734: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Bone Pain) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	56 (76.7%)	56 (77.8%)	112 (77.2%)
Last participation date < Day 78 in DB Phase	10 (13.7%)	0	10 (6.9%)
Last participation date >= Day 78 and Bone Pain Score at Week 12 not available	2 (2.7%)	4 (5.6%)	6 (4.1%)
>0% increase from baseline at Week 12	12 (16.4%)	18 (25.0%)	30 (20.7%)
<50% reduction from baseline at Week 12	39 (53.4%)	45 (62.5%)	84 (57.9%)
Return Rate (%)	86%	96%	91%
Number of Subjects in Risk	76	94	170
Return Rate in Risk (%)	97%	96%	96%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

GSK Oncology
Study GS-US-352-0101
Table 2.0734: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Bone Pain) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Bone Pain Symptom Score at Week 16			
Subjects Evaluable at Week 16, n	72	71	143
Bone Pain Score = 0 at baseline and Bone Pain Score >0 or missing at Week 16	9 (12.5%)	6 (8.5%)	15 (10.5%)
Responder, n(%)	22 (30.6%)	21 (29.6%)	43 (30.1%)
95% Exact CI	0.2024, 0.4253	0.1933, 0.4159	0.2269, 0.3829
Proportion Difference - Stratified CMH Method (95% CI)	0.01 (-0.15, 0.17)		
p-value	0.91		
Proportion Difference - Unstratified CMH Method (95% CI)	0.01 (-0.14, 0.16)		
p-value	0.90		
Proportion Difference - Unstratified Exact Method (95% CI)	0.01 (-0.15, 0.18)		
p-value	1.00		
Unadjusted Inverse Relative Risk (95% CI)	0.97 (0.59, 1.60)		
p-value [1]	0.90		
Unadjusted Inverse Odds Ratio (95% CI)	0.95 (0.47, 1.95)		
p-value [1]	0.90		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.14, 0.16)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.97 (0.59, 1.58)		
p-value [2]	0.90		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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GSK Oncology
Study GS-US-352-0101

Table 2.0734: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Bone Pain) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	50 (69.4%)	50 (70.4%)	100 (69.9%)
Last participation date < Day 106 in DB Phase	11 (15.3%)	4 (5.6%)	15 (10.5%)
Last participation date >= Day 106 and Bone Pain Score at Week 16 not available	2 (2.8%)	4 (5.6%)	6 (4.2%)
>0% increase from baseline at Week 16	15 (20.8%)	16 (22.5%)	31 (21.7%)
<50% reduction from baseline at Week 16	33 (45.8%)	38 (53.5%)	71 (49.7%)
Return Rate (%)	85%	91%	88%
Number of Subjects in Risk	75	90	165
Return Rate in Risk (%)	97%	96%	96%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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GSK Oncology
Study GS-US-352-0101
Table 2.0734: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Bone Pain) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Bone Pain Symptom Score at Week 20			
Subjects Evaluable at Week 20, n	73	72	145
Bone Pain Score = 0 at baseline and Bone Pain Score >0 or missing at Week 20	10 (13.7%)	7 (9.7%)	17 (11.7%)
Responder, n(%)	23 (31.5%)	22 (30.6%)	45 (31.0%)
95% Exact CI	0.2113, 0.4344	0.2024, 0.4253	0.2362, 0.3924
Proportion Difference - Stratified CMH Method (95% CI)	0.01 (-0.15, 0.17)		
p-value	0.90		
Proportion Difference - Unstratified CMH Method (95% CI)	0.01 (-0.14, 0.16)		
p-value	0.90		
Proportion Difference - Unstratified Exact Method (95% CI)	0.01 (-0.15, 0.18)		
p-value	1.00		
Unadjusted Inverse Relative Risk (95% CI)	0.97 (0.60, 1.58)		
p-value [1]	0.90		
Unadjusted Inverse Odds Ratio (95% CI)	0.96 (0.47, 1.93)		
p-value [1]	0.90		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.14, 0.16)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.97 (0.60, 1.57)		
p-value [2]	0.90		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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GSK Oncology

Study GS-US-352-0101

Table 2.0734: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Bone Pain) by Every 4 Weeks

Double-Blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	50 (68.5%)	50 (69.4%)	100 (69.0%)
Last participation date < Day 134 in DB Phase	12 (16.4%)	4 (5.6%)	16 (11.0%)
Last participation date >= Day 134 and Bone Pain Score at Week 20 not available	3 (4.1%)	3 (4.2%)	6 (4.1%)
>0% increase from baseline at Week 20	13 (17.8%)	17 (23.6%)	30 (20.7%)
<50% reduction from baseline at Week 20	30 (41.1%)	38 (52.8%)	68 (46.9%)
Return Rate (%)	83%	93%	88%
Number of Subjects in Risk	74	90	164
Return Rate in Risk (%)	96%	97%	96%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

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Study GS-US-352-0101
Table 2.0734: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Bone Pain) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Bone Pain Symptom Score at Week 24			
Subjects Evaluable at Week 24, n	72	74	146
Bone Pain Score = 0 at baseline and Bone Pain Score >0 or missing at Week 24	9 (12.5%)	9 (12.2%)	18 (12.3%)
Responder, n(%)	23 (31.9%)	22 (29.7%)	45 (30.8%)
95% Exact CI	0.2144, 0.4399	0.1966, 0.4148	0.2345, 0.3899
Proportion Difference - Stratified CMH Method (95% CI)	0.01 (-0.14, 0.17)		
p-value	0.86		
Proportion Difference - Unstratified CMH Method (95% CI)	0.02 (-0.13, 0.17)		
p-value	0.77		
Proportion Difference - Unstratified Exact Method (95% CI)	0.02 (-0.14, 0.18)		
p-value	0.86		
Unadjusted Inverse Relative Risk (95% CI)	0.93 (0.57, 1.51)		
p-value [1]	0.77		
Unadjusted Inverse Odds Ratio (95% CI)	0.90 (0.45, 1.82)		
p-value [1]	0.77		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.13, 0.17)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.96 (0.59, 1.54)		
p-value [2]	0.85		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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GSK Oncology
Study GS-US-352-0101
Table 2.0734: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Bone Pain) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	49 (68.1%)	52 (70.3%)	101 (69.2%)
Last participation date < Day 162 in DB Phase	16 (22.2%)	8 (10.8%)	24 (16.4%)
Last participation date >= Day 162 and Bone Pain Score at Week 24 not available	3 (4.2%)	6 (8.1%)	9 (6.2%)
>0% increase from baseline at Week 24	10 (13.9%)	16 (21.6%)	26 (17.8%)
<50% reduction from baseline at Week 24	26 (36.1%)	33 (44.6%)	59 (40.4%)
Return Rate (%)	78%	85%	82%
Number of Subjects in Risk	70	86	156
Return Rate in Risk (%)	96%	93%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-tss24-indv-gba.sas V.03.05 Output file: t-tss24-06-gba.pdf 29AUG2023: 9:58

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Table 2.0733: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Itching) by Every 4 Weeks

Double-Blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Itching Symptom Score Status			
Missing Itching Score at baseline (excluded from rate calculation)	1 (1.2%)	1 (1.1%)	2 (1.1%)
Itching Score = 0 at baseline	39 (45.3%)	33 (35.1%)	72 (40.0%)
Itching Score > 0 at baseline	46 (53.5%)	60 (63.8%)	106 (58.9%)
Response Rate of Itching Symptom Score at Week 4			
Subjects Evaluable at Week 4, n	59	69	128
Itching Score = 0 at baseline and Itching Score >0 or missing at Week 4	13 (22.0%)	9 (13.0%)	22 (17.2%)
Responder, n(%)	12 (20.3%)	25 (36.2%)	37 (28.9%)
95% Exact CI	0.1098, 0.3283	0.2499, 0.4869	0.2124, 0.3758
Proportion Difference - Stratified CMH Method (95% CI)		-0.16 (-0.33, 0.00)	
p-value		0.053	
Proportion Difference - Unstratified CMH Method (95% CI)		-0.16 (-0.31, 0.00)	
p-value		0.044	
Proportion Difference - Unstratified Exact Method (95% CI)		-0.16 (-0.33, 0.01)	
p-value		0.053	
Unadjusted Inverse Relative Risk (95% CI)		1.78 (0.98, 3.23)	
p-value [1]		0.057	
Unadjusted Inverse Odds Ratio (95% CI)		2.23 (1.00, 4.96)	
p-value [1]		0.051	
Unadjusted Absolute Risk Difference (95% CI)		-0.16 (-0.31, -0.01)	
Adjusted Inverse Relative Risk (95% CI) [2]		1.80 (1.00, 3.26)	
p-value [2]		0.051	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

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Study GS-US-352-0101

Table 2.0733: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Itching) by Every 4 Weeks

Double-Blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	47 (79.7%)	44 (63.8%)	91 (71.1%)
Last participation date < Day 21 in DB Phase	4 (6.8%)	0	4 (3.1%)
Last participation date >= Day 21 and Itching Score at Week 4 not available	4 (6.8%)	2 (2.9%)	6 (4.7%)
>0% increase from baseline at Week 4	10 (16.9%)	15 (21.7%)	25 (19.5%)
<50% reduction from baseline at Week 4	30 (50.8%)	33 (47.8%)	63 (49.2%)
Return Rate (%)	91%	98%	94%
Number of Subjects in Risk	82	94	176
Return Rate in Risk (%)	95%	98%	97%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

Table 2.0733: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Itching) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Itching Symptom Score at Week 8			
Subjects Evaluable at Week 8, n	63	66	129
Itching Score = 0 at baseline and Itching Score >0 or missing at Week 8	17 (27.0%)	6 (9.1%)	23 (17.8%)
Responder, n(%)	15 (23.8%)	34 (51.5%)	49 (38.0%)
95% Exact CI	0.1398, 0.3621	0.3888, 0.6401	0.2959, 0.4695
Proportion Difference - Stratified CMH Method (95% CI)		-0.30 (-0.46, -0.13)	
p-value		<0.001	
Proportion Difference - Unstratified CMH Method (95% CI)		-0.28 (-0.44, -0.12)	
p-value		<0.001	
Proportion Difference - Unstratified Exact Method (95% CI)		-0.28 (-0.44, -0.11)	
p-value		0.002	
Unadjusted Inverse Relative Risk (95% CI)		2.16 (1.31, 3.57)	
p-value [1]		0.002	
Unadjusted Inverse Odds Ratio (95% CI)		3.40 (1.60, 7.23)	
p-value [1]		0.001	
Unadjusted Absolute Risk Difference (95% CI)		-0.28 (-0.44, -0.12)	
Adjusted Inverse Relative Risk (95% CI) [2]		2.29 (1.40, 3.73)	
p-value [2]		<0.001	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Table 2.0733: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Itching) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	48 (76.2%)	32 (48.5%)	80 (62.0%)
Last participation date < Day 50 in DB Phase	7 (11.1%)	0	7 (5.4%)
Last participation date >= Day 50 and Itching Score at Week 8 not available	3 (4.8%)	2 (3.0%)	5 (3.9%)
>0% increase from baseline at Week 8	8 (12.7%)	12 (18.2%)	20 (15.5%)
<50% reduction from baseline at Week 8	25 (39.7%)	24 (36.4%)	49 (38.0%)
Return Rate (%)	88%	98%	93%
Number of Subjects in Risk	79	94	173
Return Rate in Risk (%)	96%	98%	97%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019
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Table 2.0733: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Itching) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Itching Symptom Score at Week 12			
Subjects Evaluable at Week 12, n	62	67	129
Itching Score = 0 at baseline and Itching Score >0 or missing at Week 12	16 (25.8%)	7 (10.4%)	23 (17.8%)
Responder, n(%)	15 (24.2%)	32 (47.8%)	47 (36.4%)
95% Exact CI	0.1422, 0.3674	0.3540, 0.6033	0.2814, 0.4536
Proportion Difference - Stratified CMH Method (95% CI)		-0.25 (-0.42, -0.08)	
p-value		0.003	
Proportion Difference - Unstratified CMH Method (95% CI)		-0.24 (-0.40, -0.07)	
p-value		0.004	
Proportion Difference - Unstratified Exact Method (95% CI)		-0.24 (-0.40, -0.06)	
p-value		0.006	
Unadjusted Inverse Relative Risk (95% CI)		1.97 (1.19, 3.28)	
p-value [1]		0.009	
Unadjusted Inverse Odds Ratio (95% CI)		2.86 (1.35, 6.09)	
p-value [1]		0.006	
Unadjusted Absolute Risk Difference (95% CI)		-0.24 (-0.40, -0.08)	
Adjusted Inverse Relative Risk (95% CI) [2]		2.05 (1.25, 3.36)	
p-value [2]		0.004	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0733: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Itching) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	47 (75.8%)	35 (52.2%)	82 (63.6%)
Last participation date < Day 78 in DB Phase	10 (16.1%)	0	10 (7.8%)
Last participation date >= Day 78 and Itching Score at Week 12 not available	2 (3.2%)	4 (6.0%)	6 (4.7%)
>0% increase from baseline at Week 12	8 (12.9%)	13 (19.4%)	21 (16.3%)
<50% reduction from baseline at Week 12	23 (37.1%)	24 (35.8%)	47 (36.4%)
Return Rate (%)	86%	96%	91%
Number of Subjects in Risk	76	94	170
Return Rate in Risk (%)	97%	96%	96%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0733: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Itching) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Itching Symptom Score at Week 16			
Subjects Evaluable at Week 16, n	63	69	132
Itching Score = 0 at baseline and Itching Score >0 or missing at Week 16	17 (27.0%)	9 (13.0%)	26 (19.7%)
Responder, n(%)	18 (28.6%)	31 (44.9%)	49 (37.1%)
95% Exact CI	0.1789, 0.4135	0.3292, 0.5738	0.2888, 0.4596
Proportion Difference - Stratified CMH Method (95% CI)	-0.18 (-0.34, -0.01)		
p-value	0.039		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.16 (-0.33, 0.00)		
p-value	0.050		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.16 (-0.33, 0.01)		
p-value	0.071		
Unadjusted Inverse Relative Risk (95% CI)	1.57 (0.98, 2.52)		
p-value [1]	0.059		
Unadjusted Inverse Odds Ratio (95% CI)	2.04 (0.99, 4.21)		
p-value [1]	0.054		
Unadjusted Absolute Risk Difference (95% CI)	-0.16 (-0.33, 0.00)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.63 (1.02, 2.59)		
p-value [2]	0.040		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

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Table 2.0733: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Itching) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	45 (71.4%)	38 (55.1%)	83 (62.9%)
Last participation date < Day 106 in DB Phase	11 (17.5%)	4 (5.8%)	15 (11.4%)
Last participation date >= Day 106 and Itching Score at Week 16 not available	2 (3.2%)	4 (5.8%)	6 (4.5%)
>0% increase from baseline at Week 16	8 (12.7%)	9 (13.0%)	17 (12.9%)
<50% reduction from baseline at Week 16	19 (30.2%)	22 (31.9%)	41 (31.1%)
Return Rate (%)	85%	91%	88%
Number of Subjects in Risk	75	90	165
Return Rate in Risk (%)	97%	96%	96%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

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Table 2.0733: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Itching) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Itching Symptom Score at Week 20			
Subjects Evaluable at Week 20, n	64	70	134
Itching Score = 0 at baseline and Itching Score >0 or missing at Week 20	18 (28.1%)	10 (14.3%)	28 (20.9%)
Responder, n(%)	17 (26.6%)	33 (47.1%)	50 (37.3%)
95% Exact CI	0.1630, 0.3909	0.3509, 0.5945	0.2912, 0.4608
Proportion Difference - Stratified CMH Method (95% CI)		-0.22 (-0.39, -0.05)	
p-value		0.009	
Proportion Difference - Unstratified CMH Method (95% CI)		-0.21 (-0.37, -0.04)	
p-value		0.012	
Proportion Difference - Unstratified Exact Method (95% CI)		-0.21 (-0.37, -0.04)	
p-value		0.020	
Unadjusted Inverse Relative Risk (95% CI)		1.77 (1.10, 2.86)	
p-value [1]		0.018	
Unadjusted Inverse Odds Ratio (95% CI)		2.47 (1.19, 5.10)	
p-value [1]		0.015	
Unadjusted Absolute Risk Difference (95% CI)		-0.21 (-0.37, -0.05)	
Adjusted Inverse Relative Risk (95% CI) [2]		1.85 (1.15, 2.95)	
p-value [2]		0.011	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-tss24-indv-gba.sas V.03.05 Output file: t-tss24-05-gba.pdf 29AUG2023: 9:57

Table 2.0733: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Itching) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	47 (73.4%)	37 (52.9%)	84 (62.7%)
Last participation date < Day 134 in DB Phase	12 (18.8%)	4 (5.7%)	16 (11.9%)
Last participation date >= Day 134 and Itching Score at Week 20 not available	3 (4.7%)	3 (4.3%)	6 (4.5%)
>0% increase from baseline at Week 20	8 (12.5%)	11 (15.7%)	19 (14.2%)
<50% reduction from baseline at Week 20	19 (29.7%)	21 (30.0%)	40 (29.9%)
Return Rate (%)	83%	93%	88%
Number of Subjects in Risk	74	90	164
Return Rate in Risk (%)	96%	97%	96%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

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Table 2.0733: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Itching) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Itching Symptom Score at Week 24			
Subjects Evaluable at Week 24, n	61	69	130
Itching Score = 0 at baseline and Itching Score >0 or missing at Week 24	15 (24.6%)	9 (13.0%)	24 (18.5%)
Responder, n(%)	15 (24.6%)	32 (46.4%)	47 (36.2%)
95% Exact CI	0.1446, 0.3729	0.3428, 0.5880	0.2791, 0.4504
Proportion Difference - Stratified CMH Method (95% CI)		-0.23 (-0.40, -0.06)	
p-value		0.008	
Proportion Difference - Unstratified CMH Method (95% CI)		-0.22 (-0.38, -0.06)	
p-value		0.008	
Proportion Difference - Unstratified Exact Method (95% CI)		-0.22 (-0.38, -0.05)	
p-value		0.011	
Unadjusted Inverse Relative Risk (95% CI)		1.89 (1.14, 3.13)	
p-value [1]		0.014	
Unadjusted Inverse Odds Ratio (95% CI)		2.65 (1.25, 5.62)	
p-value [1]		0.011	
Unadjusted Absolute Risk Difference (95% CI)		-0.22 (-0.38, -0.06)	
Adjusted Inverse Relative Risk (95% CI) [2]		1.94 (1.18, 3.18)	
p-value [2]		0.009	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019
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Table 2.0733: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Itching) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	46 (75.4%)	37 (53.6%)	83 (63.8%)
Last participation date < Day 162 in DB Phase	16 (26.2%)	8 (11.6%)	24 (18.5%)
Last participation date >= Day 162 and Itching Score at Week 24 not available	3 (4.9%)	6 (8.7%)	9 (6.9%)
>0% increase from baseline at Week 24	8 (13.1%)	12 (17.4%)	20 (15.4%)
<50% reduction from baseline at Week 24	18 (29.5%)	17 (24.6%)	35 (26.9%)
Return Rate (%)	78%	85%	82%
Number of Subjects in Risk	70	86	156
Return Rate in Risk (%)	96%	93%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

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Table 2.0732: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Night Sweats) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Night Sweats Symptom Score Status			
Missing Night Sweats Score at baseline (excluded from rate calculation)	1 (1.2%)	1 (1.1%)	2 (1.1%)
Night Sweats Score = 0 at baseline	22 (25.6%)	21 (22.3%)	43 (23.9%)
Night Sweats Score > 0 at baseline	63 (73.3%)	72 (76.6%)	135 (75.0%)
Response Rate of Night Sweats Symptom Score at Week 4			
Subjects Evaluable at Week 4, n	72	81	153
Night Sweats Score = 0 at baseline and Night Sweats Score >0 or missing at Week 4	9 (12.5%)	9 (11.1%)	18 (11.8%)
Responder, n(%)	14 (19.4%)	29 (35.8%)	43 (28.1%)
95% Exact CI	0.1106, 0.3047	0.2545, 0.4723	0.2114, 0.3593
Proportion Difference - Stratified CMH Method (95% CI)	-0.16 (-0.31, -0.02)		
p-value	0.030		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.16 (-0.30, -0.02)		
p-value	0.022		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.16 (-0.32, 0.00)		
p-value	0.031		
Unadjusted Inverse Relative Risk (95% CI)	1.84 (1.06, 3.20)		
p-value [1]	0.031		
Unadjusted Inverse Odds Ratio (95% CI)	2.31 (1.10, 4.84)		
p-value [1]	0.026		
Unadjusted Absolute Risk Difference (95% CI)	-0.16 (-0.30, -0.02)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.84 (1.06, 3.19)		
p-value [2]	0.030		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0732: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Night Sweats) by Every 4 Weeks

Double-Blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	58 (80.6%)	52 (64.2%)	110 (71.9%)
Last participation date < Day 21 in DB Phase	3 (4.2%)	0	3 (2.0%)
Last participation date >= Day 21 and Night Sweats Score at Week 4 not available	4 (5.6%)	2 (2.5%)	6 (3.9%)
>0% increase from baseline at Week 4	17 (23.6%)	7 (8.6%)	24 (15.7%)
<50% reduction from baseline at Week 4	46 (63.9%)	41 (50.6%)	87 (56.9%)
Return Rate (%)	92%	98%	95%
Number of Subjects in Risk	83	94	177
Return Rate in Risk (%)	95%	98%	97%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0732: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Night Sweats) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Night Sweats Symptom Score at Week 8			
Subjects Evaluable at Week 8, n	75	78	153
Night Sweats Score = 0 at baseline and Night Sweats Score >0 or missing at Week 8	12 (16.0%)	6 (7.7%)	18 (11.8%)
Responder, n(%)	27 (36.0%)	40 (51.3%)	67 (43.8%)
95% Exact CI	0.2523, 0.4791	0.3969, 0.6277	0.3579, 0.5203
Proportion Difference - Stratified CMH Method (95% CI)	-0.18 (-0.34, -0.02)		
p-value	0.030		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.15 (-0.31, 0.00)		
p-value	0.055		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.15 (-0.31, 0.01)		
p-value	0.073		
Unadjusted Inverse Relative Risk (95% CI)	1.42 (0.98, 2.06)		
p-value [1]	0.062		
Unadjusted Inverse Odds Ratio (95% CI)	1.87 (0.98, 3.58)		
p-value [1]	0.058		
Unadjusted Absolute Risk Difference (95% CI)	-0.15 (-0.31, 0.00)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.50 (1.04, 2.17)		
p-value [2]	0.028		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0732: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Night Sweats) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	48 (64.0%)	38 (48.7%)	86 (56.2%)
Last participation date < Day 50 in DB Phase	7 (9.3%)	0	7 (4.6%)
Last participation date >= Day 50 and Night Sweats Score at Week 8 not available	3 (4.0%)	2 (2.6%)	5 (3.3%)
>0% increase from baseline at Week 8	14 (18.7%)	9 (11.5%)	23 (15.0%)
<50% reduction from baseline at Week 8	31 (41.3%)	30 (38.5%)	61 (39.9%)
Return Rate (%)	88%	98%	93%
Number of Subjects in Risk	79	94	173
Return Rate in Risk (%)	96%	98%	97%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0732: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Night Sweats) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Night Sweats Symptom Score at Week 12			
Subjects Evaluable at Week 12, n	71	80	151
Night Sweats Score = 0 at baseline and Night Sweats Score >0 or missing at Week 12	8 (11.3%)	8 (10.0%)	16 (10.6%)
Responder, n(%)	26 (36.6%)	41 (51.3%)	67 (44.4%)
95% Exact CI	0.2550, 0.4890	0.3981, 0.6259	0.3630, 0.5267
Proportion Difference - Stratified CMH Method (95% CI)	-0.16 (-0.32, 0.00)		
p-value	0.051		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.15 (-0.30, 0.01)		
p-value	0.069		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.15 (-0.30, 0.01)		
p-value	0.074		
Unadjusted Inverse Relative Risk (95% CI)	1.40 (0.96, 2.03)		
p-value [1]	0.078		
Unadjusted Inverse Odds Ratio (95% CI)	1.82 (0.95, 3.49)		
p-value [1]	0.072		
Unadjusted Absolute Risk Difference (95% CI)	-0.15 (-0.30, 0.01)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.44 (1.00, 2.08)		
p-value [2]	0.051		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0732: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Night Sweats) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	45 (63.4%)	39 (48.8%)	84 (55.6%)
Last participation date < Day 78 in DB Phase	10 (14.1%)	0	10 (6.6%)
Last participation date >= Day 78 and Night Sweats Score at Week 12 not available	2 (2.8%)	4 (5.0%)	6 (4.0%)
>0% increase from baseline at Week 12	11 (15.5%)	9 (11.3%)	20 (13.2%)
<50% reduction from baseline at Week 12	30 (42.3%)	27 (33.8%)	57 (37.7%)
Return Rate (%)	86%	96%	91%
Number of Subjects in Risk	76	94	170
Return Rate in Risk (%)	97%	96%	96%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0732: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Night Sweats) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Night Sweats Symptom Score at Week 16			
Subjects Evaluable at Week 16, n	70	80	150
Night Sweats Score = 0 at baseline and Night Sweats Score >0 or missing at Week 16	7 (10.0%)	8 (10.0%)	15 (10.0%)
Responder, n(%)	28 (40.0%)	40 (50.0%)	68 (45.3%)
95% Exact CI	0.2847, 0.5241	0.3860, 0.6140	0.3720, 0.5366
Proportion Difference - Stratified CMH Method (95% CI)	-0.12 (-0.28, 0.05)		
p-value	0.16		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.10 (-0.26, 0.06)		
p-value	0.22		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.10 (-0.26, 0.06)		
p-value	0.25		
Unadjusted Inverse Relative Risk (95% CI)	1.25 (0.87, 1.79)		
p-value [1]	0.23		
Unadjusted Inverse Odds Ratio (95% CI)	1.50 (0.78, 2.87)		
p-value [1]	0.22		
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.26, 0.06)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.29 (0.91, 1.84)		
p-value [2]	0.16		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0732: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Night Sweats) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	42 (60.0%)	40 (50.0%)	82 (54.7%)
Last participation date < Day 106 in DB Phase	10 (14.3%)	4 (5.0%)	14 (9.3%)
Last participation date >= Day 106 and Night Sweats Score at Week 16 not available	2 (2.9%)	4 (5.0%)	6 (4.0%)
>0% increase from baseline at Week 16	13 (18.6%)	9 (11.3%)	22 (14.7%)
<50% reduction from baseline at Week 16	28 (40.0%)	26 (32.5%)	54 (36.0%)
Return Rate (%)	86%	91%	89%
Number of Subjects in Risk	76	90	166
Return Rate in Risk (%)	97%	96%	96%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0732: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Night Sweats) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Night Sweats Symptom Score at Week 20			
Subjects Evaluable at Week 20, n	70	80	150
Night Sweats Score = 0 at baseline and Night Sweats Score >0 or missing at Week 20	7 (10.0%)	8 (10.0%)	15 (10.0%)
Responder, n(%)	25 (35.7%)	40 (50.0%)	65 (43.3%)
95% Exact CI	0.2461, 0.4807	0.3860, 0.6140	0.3527, 0.5166
Proportion Difference - Stratified CMH Method (95% CI)	-0.15 (-0.31, 0.01)		
p-value	0.062		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.14 (-0.30, 0.02)		
p-value	0.076		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.14 (-0.30, 0.02)		
p-value	0.099		
Unadjusted Inverse Relative Risk (95% CI)	1.40 (0.95, 2.05)		
p-value [1]	0.085		
Unadjusted Inverse Odds Ratio (95% CI)	1.80 (0.93, 3.47)		
p-value [1]	0.079		
Unadjusted Absolute Risk Difference (95% CI)	-0.14 (-0.30, 0.01)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.43 (0.98, 2.08)		
p-value [2]	0.064		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0732: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Night Sweats) by Every 4 Weeks

Double-Blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	45 (64.3%)	40 (50.0%)	85 (56.7%)
Last participation date < Day 134 in DB Phase	11 (15.7%)	4 (5.0%)	15 (10.0%)
Last participation date >= Day 134 and Night Sweats Score at Week 20 not available	3 (4.3%)	3 (3.8%)	6 (4.0%)
>0% increase from baseline at Week 20	11 (15.7%)	9 (11.3%)	20 (13.3%)
<50% reduction from baseline at Week 20	29 (41.4%)	27 (33.8%)	56 (37.3%)
Return Rate (%)	84%	93%	88%
Number of Subjects in Risk	75	90	165
Return Rate in Risk (%)	96%	97%	96%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0732: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Night Sweats) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Night Sweats Symptom Score at Week 24			
Subjects Evaluable at Week 24, n	69	80	149
Night Sweats Score = 0 at baseline and Night Sweats Score >0 or missing at Week 24	6 (8.7%)	8 (10.0%)	14 (9.4%)
Responder, n(%)	28 (40.6%)	41 (51.3%)	69 (46.3%)
95% Exact CI	0.2891, 0.5308	0.3981, 0.6259	0.3811, 0.5465
Proportion Difference - Stratified CMH Method (95% CI)	-0.11 (-0.27, 0.06)		
p-value	0.20		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.11 (-0.27, 0.05)		
p-value	0.19		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.11 (-0.26, 0.06)		
p-value	0.25		
Unadjusted Inverse Relative Risk (95% CI)	1.26 (0.88, 1.80)		
p-value [1]	0.20		
Unadjusted Inverse Odds Ratio (95% CI)	1.54 (0.80, 2.95)		
p-value [1]	0.19		
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.27, 0.05)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.27 (0.89, 1.81)		
p-value [2]	0.19		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0732: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Night Sweats) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	41 (59.4%)	39 (48.8%)	80 (53.7%)
Last participation date < Day 162 in DB Phase	16 (23.2%)	8 (10.0%)	24 (16.1%)
Last participation date >= Day 162 and Night Sweats Score at Week 24 not available	3 (4.3%)	6 (7.5%)	9 (6.0%)
>0% increase from baseline at Week 24	10 (14.5%)	8 (10.0%)	18 (12.1%)
<50% reduction from baseline at Week 24	21 (30.4%)	20 (25.0%)	41 (27.5%)
Return Rate (%)	78%	85%	82%
Number of Subjects in Risk	70	86	156
Return Rate in Risk (%)	96%	93%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0731: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Ab Discomfort) by Every 4 Weeks

Double-Blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Ab Discomfort Symptom Score Status			
Missing Ab Discomfort Score at baseline (excluded from rate calculation)	1 (1.2%)	1 (1.1%)	2 (1.1%)
Ab Discomfort Score = 0 at baseline	22 (25.6%)	10 (10.6%)	32 (17.8%)
Ab Discomfort Score > 0 at baseline	63 (73.3%)	83 (88.3%)	146 (81.1%)
Response Rate of Ab Discomfort Symptom Score at Week 4			
Subjects Evaluable at Week 4, n	74	89	163
Ab Discomfort Score = 0 at baseline and Ab Discomfort Score >0 or missing at Week 4	11 (14.9%)	6 (6.7%)	17 (10.4%)
Responder, n(%)	12 (16.2%)	16 (18.0%)	28 (17.2%)
95% Exact CI	0.0867, 0.2661	0.1064, 0.2755	0.1173, 0.2386
Proportion Difference - Stratified CMH Method (95% CI)		-0.01 (-0.14, 0.11)	
p-value		0.84	
Proportion Difference - Unstratified CMH Method (95% CI)		-0.02 (-0.14, 0.10)	
p-value		0.77	
Proportion Difference - Unstratified Exact Method (95% CI)		-0.02 (-0.17, 0.14)	
p-value		0.84	
Unadjusted Inverse Relative Risk (95% CI)		1.11 (0.56, 2.19)	
p-value [1]		0.77	
Unadjusted Inverse Odds Ratio (95% CI)		1.13 (0.50, 2.57)	
p-value [1]		0.77	
Unadjusted Absolute Risk Difference (95% CI)		-0.02 (-0.13, 0.10)	
Adjusted Inverse Relative Risk (95% CI) [2]		1.08 (0.55, 2.13)	
p-value [2]		0.83	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0731: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Ab Discomfort) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	62 (83.8%)	73 (82.0%)	135 (82.8%)
Last participation date < Day 21 in DB Phase	3 (4.1%)	0	3 (1.8%)
Last participation date >= Day 21 and Ab Discomfort Score at Week 4 not available	4 (5.4%)	2 (2.2%)	6 (3.7%)
>0% increase from baseline at Week 4	14 (18.9%)	25 (28.1%)	39 (23.9%)
<50% reduction from baseline at Week 4	47 (63.5%)	65 (73.0%)	112 (68.7%)
Return Rate (%)	92%	98%	95%
Number of Subjects in Risk	83	94	177
Return Rate in Risk (%)	95%	98%	97%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0731: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Ab Discomfort) by Every 4 Weeks

Double-Blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Ab Discomfort Symptom Score at Week 8			
Subjects Evaluable at Week 8, n	75	89	164
Ab Discomfort Score = 0 at baseline and Ab Discomfort Score >0 or missing at Week 8	12 (16.0%)	6 (6.7%)	18 (11.0%)
Responder, n(%)	19 (25.3%)	22 (24.7%)	41 (25.0%)
95% Exact CI	0.1599, 0.3670	0.1619, 0.3500	0.1858, 0.3235
Proportion Difference - Stratified CMH Method (95% CI)	0.00 (-0.15, 0.14)		
p-value	0.95		
Proportion Difference - Unstratified CMH Method (95% CI)	0.01 (-0.13, 0.14)		
p-value	0.93		
Proportion Difference - Unstratified Exact Method (95% CI)	0.01 (-0.15, 0.16)		
p-value	1.00		
Unadjusted Inverse Relative Risk (95% CI)	0.98 (0.57, 1.66)		
p-value [1]	0.93		
Unadjusted Inverse Odds Ratio (95% CI)	0.97 (0.48, 1.97)		
p-value [1]	0.93		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.13, 0.14)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.02 (0.60, 1.73)		
p-value [2]	0.95		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0731: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Ab Discomfort) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	56 (74.7%)	67 (75.3%)	123 (75.0%)
Last participation date < Day 50 in DB Phase	7 (9.3%)	0	7 (4.3%)
Last participation date >= Day 50 and Ab Discomfort Score at Week 8 not available	3 (4.0%)	2 (2.2%)	5 (3.0%)
>0% increase from baseline at Week 8	14 (18.7%)	20 (22.5%)	34 (20.7%)
<50% reduction from baseline at Week 8	39 (52.0%)	59 (66.3%)	98 (59.8%)
Return Rate (%)	88%	98%	93%
Number of Subjects in Risk	79	94	173
Return Rate in Risk (%)	96%	98%	97%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0731: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Ab Discomfort) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Ab Discomfort Symptom Score at Week 12			
Subjects Evaluable at Week 12, n	77	89	166
Ab Discomfort Score = 0 at baseline and Ab Discomfort Score >0 or missing at Week 12	14 (18.2%)	6 (6.7%)	20 (12.0%)
Responder, n(%)	19 (24.7%)	29 (32.6%)	48 (28.9%)
95% Exact CI	0.1556, 0.3582	0.2302, 0.4334	0.2215, 0.3645
Proportion Difference - Stratified CMH Method (95% CI)	-0.09 (-0.23, 0.06)		
p-value	0.24		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.08 (-0.22, 0.06)		
p-value	0.26		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.08 (-0.23, 0.07)		
p-value	0.30		
Unadjusted Inverse Relative Risk (95% CI)	1.32 (0.81, 2.16)		
p-value [1]	0.27		
Unadjusted Inverse Odds Ratio (95% CI)	1.48 (0.75, 2.92)		
p-value [1]	0.26		
Unadjusted Absolute Risk Difference (95% CI)	-0.08 (-0.22, 0.06)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.36 (0.83, 2.23)		
p-value [2]	0.22		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0731: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Ab Discomfort) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	58 (75.3%)	60 (67.4%)	118 (71.1%)
Last participation date < Day 78 in DB Phase	10 (13.0%)	0	10 (6.0%)
Last participation date >= Day 78 and Ab Discomfort Score at Week 12 not available	2 (2.6%)	4 (4.5%)	6 (3.6%)
>0% increase from baseline at Week 12	12 (15.6%)	17 (19.1%)	29 (17.5%)
<50% reduction from baseline at Week 12	37 (48.1%)	50 (56.2%)	87 (52.4%)
Return Rate (%)	86%	96%	91%
Number of Subjects in Risk	76	94	170
Return Rate in Risk (%)	97%	96%	96%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0731: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Ab Discomfort) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Ab Discomfort Symptom Score at Week 16			
Subjects Evaluable at Week 16, n	78	90	168
Ab Discomfort Score = 0 at baseline and Ab Discomfort Score >0 or missing at Week 16	15 (19.2%)	7 (7.8%)	22 (13.1%)
Responder, n(%)	22 (28.2%)	33 (36.7%)	55 (32.7%)
95% Exact CI	0.1859, 0.3953	0.2675, 0.4749	0.2571, 0.4039
Proportion Difference - Stratified CMH Method (95% CI)	-0.09 (-0.24, 0.06)		
p-value	0.23		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.08 (-0.23, 0.06)		
p-value	0.24		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.08 (-0.23, 0.07)		
p-value	0.25		
Unadjusted Inverse Relative Risk (95% CI)	1.30 (0.83, 2.03)		
p-value [1]	0.25		
Unadjusted Inverse Odds Ratio (95% CI)	1.47 (0.77, 2.83)		
p-value [1]	0.24		
Unadjusted Absolute Risk Difference (95% CI)	-0.08 (-0.23, 0.06)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.32 (0.85, 2.06)		
p-value [2]	0.21		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0731: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Ab Discomfort) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	56 (71.8%)	57 (63.3%)	113 (67.3%)
Last participation date < Day 106 in DB Phase	10 (12.8%)	4 (4.4%)	14 (8.3%)
Last participation date >= Day 106 and Ab Discomfort Score at Week 16 not available	2 (2.6%)	4 (4.4%)	6 (3.6%)
>0% increase from baseline at Week 16	15 (19.2%)	16 (17.8%)	31 (18.5%)
<50% reduction from baseline at Week 16	34 (43.6%)	43 (47.8%)	77 (45.8%)
Return Rate (%)	86%	91%	89%
Number of Subjects in Risk	76	90	166
Return Rate in Risk (%)	97%	96%	96%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0731: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Ab Discomfort) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Ab Discomfort Symptom Score at Week 20			
Subjects Evaluable at Week 20, n	75	89	164
Ab Discomfort Score = 0 at baseline and Ab Discomfort Score >0 or missing at Week 20	12 (16.0%)	6 (6.7%)	18 (11.0%)
Responder, n(%)	21 (28.0%)	31 (34.8%)	52 (31.7%)
95% Exact CI	0.1824, 0.3956	0.2504, 0.4567	0.2467, 0.3942
Proportion Difference - Stratified CMH Method (95% CI)	-0.07 (-0.22, 0.08)		
p-value	0.38		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.07 (-0.21, 0.07)		
p-value	0.35		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.07 (-0.22, 0.09)		
p-value	0.40		
Unadjusted Inverse Relative Risk (95% CI)	1.24 (0.78, 1.97)		
p-value [1]	0.35		
Unadjusted Inverse Odds Ratio (95% CI)	1.37 (0.71, 2.68)		
p-value [1]	0.35		
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.21, 0.07)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.24 (0.78, 1.96)		
p-value [2]	0.36		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0731: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Ab Discomfort) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	54 (72.0%)	58 (65.2%)	112 (68.3%)
Last participation date < Day 134 in DB Phase	11 (14.7%)	4 (4.5%)	15 (9.1%)
Last participation date >= Day 134 and Ab Discomfort Score at Week 20 not available	3 (4.0%)	3 (3.4%)	6 (3.7%)
>0% increase from baseline at Week 20	11 (14.7%)	18 (20.2%)	29 (17.7%)
<50% reduction from baseline at Week 20	33 (44.0%)	46 (51.7%)	79 (48.2%)
Return Rate (%)	84%	93%	88%
Number of Subjects in Risk	75	90	165
Return Rate in Risk (%)	96%	97%	96%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0731: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Ab Discomfort) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Ab Discomfort Symptom Score at Week 24			
Subjects Evaluable at Week 24, n	75	87	162
Ab Discomfort Score = 0 at baseline and Ab Discomfort Score >0 or missing at Week 24	12 (16.0%)	4 (4.6%)	16 (9.9%)
Responder, n(%)	18 (24.0%)	32 (36.8%)	50 (30.9%)
95% Exact CI	0.1489, 0.3525	0.2669, 0.4780	0.2385, 0.3859
Proportion Difference - Stratified CMH Method (95% CI)		-0.13 (-0.28, 0.02)	
p-value		0.082	
Proportion Difference - Unstratified CMH Method (95% CI)		-0.13 (-0.27, 0.01)	
p-value		0.076	
Proportion Difference - Unstratified Exact Method (95% CI)		-0.13 (-0.28, 0.03)	
p-value		0.090	
Unadjusted Inverse Relative Risk (95% CI)		1.53 (0.94, 2.50)	
p-value [1]		0.086	
Unadjusted Inverse Odds Ratio (95% CI)		1.84 (0.93, 3.66)	
p-value [1]		0.081	
Unadjusted Absolute Risk Difference (95% CI)		-0.13 (-0.27, 0.01)	
Adjusted Inverse Relative Risk (95% CI) [2]		1.55 (0.95, 2.51)	
p-value [2]		0.078	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0731: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Ab Discomfort) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	57 (76.0%)	55 (63.2%)	112 (69.1%)
Last participation date < Day 162 in DB Phase	16 (21.3%)	8 (9.2%)	24 (14.8%)
Last participation date >= Day 162 and Ab Discomfort Score at Week 24 not available	3 (4.0%)	6 (6.9%)	9 (5.6%)
>0% increase from baseline at Week 24	14 (18.7%)	16 (18.4%)	30 (18.5%)
<50% reduction from baseline at Week 24	31 (41.3%)	38 (43.7%)	69 (42.6%)
Return Rate (%)	78%	85%	82%
Number of Subjects in Risk	70	86	156
Return Rate in Risk (%)	96%	93%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0730: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Early Satiety) by Every 4 Weeks

Double-Blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Early Satiety Symptom Score Status			
Missing Early Satiety Score at baseline (excluded from rate calculation)	1 (1.2%)	1 (1.1%)	2 (1.1%)
Early Satiety Score = 0 at baseline	11 (12.8%)	12 (12.8%)	23 (12.8%)
Early Satiety Score > 0 at baseline	74 (86.0%)	81 (86.2%)	155 (86.1%)
Response Rate of Early Satiety Symptom Score at Week 4			
Subjects Evaluable at Week 4, n	79	84	163
Early Satiety Score = 0 at baseline and Early Satiety Score >0 or missing at Week 4	5 (6.3%)	3 (3.6%)	8 (4.9%)
Responder, n(%)	14 (17.7%)	19 (22.6%)	33 (20.2%)
95% Exact CI	0.1004, 0.2794	0.1420, 0.3305	0.1436, 0.2724
Proportion Difference - Stratified CMH Method (95% CI)	-0.04 (-0.18, 0.09)		
p-value	0.51		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.05 (-0.17, 0.08)		
p-value	0.44		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.05 (-0.20, 0.11)		
p-value	0.56		
Unadjusted Inverse Relative Risk (95% CI)	1.28 (0.69, 2.37)		
p-value [1]	0.44		
Unadjusted Inverse Odds Ratio (95% CI)	1.36 (0.63, 2.93)		
p-value [1]	0.44		
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.17, 0.07)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.25 (0.67, 2.34)		
p-value [2]	0.49		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0730: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Early Satiety) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	65 (82.3%)	65 (77.4%)	130 (79.8%)
Last participation date < Day 21 in DB Phase	3 (3.8%)	0	3 (1.8%)
Last participation date >= Day 21 and Early Satiety Score at Week 4 not available	4 (5.1%)	2 (2.4%)	6 (3.7%)
>0% increase from baseline at Week 4	21 (26.6%)	19 (22.6%)	40 (24.5%)
<50% reduction from baseline at Week 4	53 (67.1%)	60 (71.4%)	113 (69.3%)
Return Rate (%)	92%	98%	95%
Number of Subjects in Risk	83	94	177
Return Rate in Risk (%)	95%	98%	97%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0730: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Early Satiety) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Early Satiety Symptom Score at Week 8			
Subjects Evaluable at Week 8, n	77	82	159
Early Satiety Score = 0 at baseline and Early Satiety Score >0 or missing at Week 8	3 (3.9%)	1 (1.2%)	4 (2.5%)
Responder, n(%)	24 (31.2%)	28 (34.1%)	52 (32.7%)
95% Exact CI	0.2109, 0.4274	0.2403, 0.4545	0.2548, 0.4058
Proportion Difference - Stratified CMH Method (95% CI)	-0.03 (-0.18, 0.13)		
p-value	0.72		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.03 (-0.18, 0.12)		
p-value	0.69		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.03 (-0.18, 0.13)		
p-value	0.74		
Unadjusted Inverse Relative Risk (95% CI)	1.10 (0.70, 1.71)		
p-value [1]	0.69		
Unadjusted Inverse Odds Ratio (95% CI)	1.15 (0.59, 2.22)		
p-value [1]	0.69		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.18, 0.12)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.09 (0.69, 1.72)		
p-value [2]	0.70		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0730: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Early Satiety) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	53 (68.8%)	54 (65.9%)	107 (67.3%)
Last participation date < Day 50 in DB Phase	7 (9.1%)	0	7 (4.4%)
Last participation date >= Day 50 and Early Satiety Score at Week 8 not available	3 (3.9%)	2 (2.4%)	5 (3.1%)
>0% increase from baseline at Week 8	14 (18.2%)	14 (17.1%)	28 (17.6%)
<50% reduction from baseline at Week 8	40 (51.9%)	51 (62.2%)	91 (57.2%)
Return Rate (%)	88%	98%	93%
Number of Subjects in Risk	79	94	173
Return Rate in Risk (%)	96%	98%	97%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0730: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Early Satiety) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Early Satiety Symptom Score at Week 12			
Subjects Evaluable at Week 12, n	76	84	160
Early Satiety Score = 0 at baseline and Early Satiety Score >0 or missing at Week 12	2 (2.6%)	3 (3.6%)	5 (3.1%)
Responder, n(%)	29 (38.2%)	31 (36.9%)	60 (37.5%)
95% Exact CI	0.2725, 0.5002	0.2663, 0.4813	0.2998, 0.4549
Proportion Difference - Stratified CMH Method (95% CI)	0.00 (-0.16, 0.15)		
p-value	0.98		
Proportion Difference - Unstratified CMH Method (95% CI)	0.01 (-0.14, 0.16)		
p-value	0.87		
Proportion Difference - Unstratified Exact Method (95% CI)	0.01 (-0.14, 0.17)		
p-value	0.87		
Unadjusted Inverse Relative Risk (95% CI)	0.97 (0.65, 1.44)		
p-value [1]	0.87		
Unadjusted Inverse Odds Ratio (95% CI)	0.95 (0.50, 1.80)		
p-value [1]	0.87		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.14, 0.16)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.01 (0.68, 1.50)		
p-value [2]	0.98		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0730: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Early Satiety) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	47 (61.8%)	53 (63.1%)	100 (62.5%)
Last participation date < Day 78 in DB Phase	10 (13.2%)	0	10 (6.3%)
Last participation date >= Day 78 and Early Satiety Score at Week 12 not available	2 (2.6%)	4 (4.8%)	6 (3.8%)
>0% increase from baseline at Week 12	11 (14.5%)	13 (15.5%)	24 (15.0%)
<50% reduction from baseline at Week 12	33 (43.4%)	46 (54.8%)	79 (49.4%)
Return Rate (%)	86%	96%	91%
Number of Subjects in Risk	76	94	170
Return Rate in Risk (%)	97%	96%	96%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0730: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Early Satiety) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Early Satiety Symptom Score at Week 16			
Subjects Evaluable at Week 16, n	76	83	159
Early Satiety Score = 0 at baseline and Early Satiety Score >0 or missing at Week 16	2 (2.6%)	2 (2.4%)	4 (2.5%)
Responder, n(%)	26 (34.2%)	32 (38.6%)	58 (36.5%)
95% Exact CI	0.2371, 0.4599	0.2807, 0.4988	0.2900, 0.4447
Proportion Difference - Stratified CMH Method (95% CI)	-0.04 (-0.19, 0.12)		
p-value	0.63		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.04 (-0.19, 0.11)		
p-value	0.57		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.04 (-0.20, 0.11)		
p-value	0.62		
Unadjusted Inverse Relative Risk (95% CI)	1.13 (0.75, 1.70)		
p-value [1]	0.57		
Unadjusted Inverse Odds Ratio (95% CI)	1.21 (0.63, 2.31)		
p-value [1]	0.57		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.19, 0.11)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.11 (0.74, 1.67)		
p-value [2]	0.61		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0730: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Early Satiety) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	50 (65.8%)	51 (61.4%)	101 (63.5%)
Last participation date < Day 106 in DB Phase	11 (14.5%)	4 (4.8%)	15 (9.4%)
Last participation date >= Day 106 and Early Satiety Score at Week 16 not available	2 (2.6%)	4 (4.8%)	6 (3.8%)
>0% increase from baseline at Week 16	19 (25.0%)	11 (13.3%)	30 (18.9%)
<50% reduction from baseline at Week 16	35 (46.1%)	41 (49.4%)	76 (47.8%)
Return Rate (%)	85%	91%	88%
Number of Subjects in Risk	75	90	165
Return Rate in Risk (%)	97%	96%	96%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0730: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Early Satiety) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Early Satiety Symptom Score at Week 20			
Subjects Evaluable at Week 20, n	76	83	159
Early Satiety Score = 0 at baseline and Early Satiety Score >0 or missing at Week 20	2 (2.6%)	2 (2.4%)	4 (2.5%)
Responder, n(%)	27 (35.5%)	32 (38.6%)	59 (37.1%)
95% Exact CI	0.2488, 0.4734	0.2807, 0.4988	0.2959, 0.4512
Proportion Difference - Stratified CMH Method (95% CI)	-0.03 (-0.19, 0.13)		
p-value	0.73		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.03 (-0.18, 0.12)		
p-value	0.69		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.03 (-0.19, 0.13)		
p-value	0.74		
Unadjusted Inverse Relative Risk (95% CI)	1.09 (0.72, 1.63)		
p-value [1]	0.69		
Unadjusted Inverse Odds Ratio (95% CI)	1.14 (0.60, 2.17)		
p-value [1]	0.69		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.18, 0.12)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.08 (0.72, 1.62)		
p-value [2]	0.72		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0730: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Early Satiety) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	49 (64.5%)	51 (61.4%)	100 (62.9%)
Last participation date < Day 134 in DB Phase	12 (15.8%)	4 (4.8%)	16 (10.1%)
Last participation date >= Day 134 and Early Satiety Score at Week 20 not available	3 (3.9%)	3 (3.6%)	6 (3.8%)
>0% increase from baseline at Week 20	17 (22.4%)	14 (16.9%)	31 (19.5%)
<50% reduction from baseline at Week 20	32 (42.1%)	42 (50.6%)	74 (46.5%)
Return Rate (%)	83%	93%	88%
Number of Subjects in Risk	74	90	164
Return Rate in Risk (%)	96%	97%	96%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0730: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Early Satiety) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Early Satiety Symptom Score at Week 24			
Subjects Evaluable at Week 24, n	75	84	159
Early Satiety Score = 0 at baseline and Early Satiety Score >0 or missing at Week 24	1 (1.3%)	3 (3.6%)	4 (2.5%)
Responder, n(%)	25 (33.3%)	31 (36.9%)	56 (35.2%)
95% Exact CI	0.2286, 0.4517	0.2663, 0.4813	0.2782, 0.4318
Proportion Difference - Stratified CMH Method (95% CI)	-0.04 (-0.19, 0.12)		
p-value	0.65		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.04 (-0.19, 0.11)		
p-value	0.64		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.04 (-0.19, 0.12)		
p-value	0.74		
Unadjusted Inverse Relative Risk (95% CI)	1.11 (0.72, 1.69)		
p-value [1]	0.64		
Unadjusted Inverse Odds Ratio (95% CI)	1.17 (0.61, 2.25)		
p-value [1]	0.64		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.18, 0.11)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.11 (0.73, 1.69)		
p-value [2]	0.63		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0730: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Early Satiety) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	50 (66.7%)	53 (63.1%)	103 (64.8%)
Last participation date < Day 162 in DB Phase	16 (21.3%)	8 (9.5%)	24 (15.1%)
Last participation date >= Day 162 and Early Satiety Score at Week 24 not available	3 (4.0%)	6 (7.1%)	9 (5.7%)
>0% increase from baseline at Week 24	17 (22.7%)	12 (14.3%)	29 (18.2%)
<50% reduction from baseline at Week 24	30 (40.0%)	36 (42.9%)	66 (41.5%)
Return Rate (%)	78%	85%	82%
Number of Subjects in Risk	70	86	156
Return Rate in Risk (%)	96%	93%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

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Table 2.0729: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Tiredness) by Every 4 Weeks

Double-Blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Tiredness Symptom Score Status			
Missing Tiredness Score at baseline (excluded from rate calculation)	1 (1.2%)	1 (1.1%)	2 (1.1%)
Tiredness Score = 0 at baseline	5 (5.8%)	1 (1.1%)	6 (3.3%)
Tiredness Score > 0 at baseline	80 (93.0%)	92 (97.9%)	172 (95.6%)
Response Rate of Tiredness Symptom Score at Week 4			
Subjects Evaluable at Week 4, n	84	93	177
Tiredness Score = 0 at baseline and Tiredness Score >0 or missing at Week 4	4 (4.8%)	1 (1.1%)	5 (2.8%)
Responder, n(%)	5 (6.0%)	17 (18.3%)	22 (12.4%)
95% Exact CI	0.0196, 0.1335	0.1102, 0.2765	0.0796, 0.1821
Proportion Difference - Stratified CMH Method (95% CI)	-0.12 (-0.23, -0.01)		
p-value	0.030		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.12 (-0.22, -0.03)		
p-value	0.011		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.12 (-0.27, 0.02)		
p-value	0.021		
Unadjusted Inverse Relative Risk (95% CI)	3.07 (1.18, 7.96)		
p-value [1]	0.021		
Unadjusted Inverse Odds Ratio (95% CI)	3.53 (1.24, 10.06)		
p-value [1]	0.018		
Unadjusted Absolute Risk Difference (95% CI)	-0.12 (-0.22, -0.03)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

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Table 2.0729: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Tiredness) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	79 (94.0%)	76 (81.7%)	155 (87.6%)
Last participation date < Day 21 in DB Phase	4 (4.8%)	0	4 (2.3%)
Last participation date >= Day 21 and Tiredness Score at Week 4 not available	4 (4.8%)	2 (2.2%)	6 (3.4%)
>0% increase from baseline at Week 4	24 (28.6%)	20 (21.5%)	44 (24.9%)
<50% reduction from baseline at Week 4	67 (79.8%)	73 (78.5%)	140 (79.1%)
Return Rate (%)	91%	98%	94%
Number of Subjects in Risk	82	94	176
Return Rate in Risk (%)	95%	98%	97%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 01JUL2019
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Study GS-US-352-0101

Table 2.0729: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Tiredness) by Every 4 Weeks

Double-Blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Tiredness Symptom Score at Week 8			
Subjects Evaluable at Week 8, n	85	93	178
Tiredness Score = 0 at baseline and Tiredness Score >0 or missing at Week 8	5 (5.9%)	1 (1.1%)	6 (3.4%)
Responder, n(%)	10 (11.8%)	21 (22.6%)	31 (17.4%)
95% Exact CI	0.0579, 0.2057	0.1455, 0.3242	0.1215, 0.2380
Proportion Difference - Stratified CMH Method (95% CI)	-0.12 (-0.24, 0.00)		
p-value	0.057		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.11 (-0.22, 0.00)		
p-value	0.056		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.11 (-0.25, 0.04)		
p-value	0.075		
Unadjusted Inverse Relative Risk (95% CI)	1.92 (0.96, 3.84)		
p-value [1]	0.065		
Unadjusted Inverse Odds Ratio (95% CI)	2.19 (0.96, 4.96)		
p-value [1]	0.061		
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.22, 0.00)		
Adjusted Inverse Relative Risk (95% CI) [2]	2.01 (1.00, 4.06)		
p-value [2]	0.051		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

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Table 2.0729: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Tiredness) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	75 (88.2%)	72 (77.4%)	147 (82.6%)
Last participation date < Day 50 in DB Phase	7 (8.2%)	0	7 (3.9%)
Last participation date >= Day 50 and Tiredness Score at Week 8 not available	3 (3.5%)	2 (2.2%)	5 (2.8%)
>0% increase from baseline at Week 8	23 (27.1%)	27 (29.0%)	50 (28.1%)
<50% reduction from baseline at Week 8	60 (70.6%)	69 (74.2%)	129 (72.5%)
Return Rate (%)	88%	98%	93%
Number of Subjects in Risk	79	94	173
Return Rate in Risk (%)	96%	98%	97%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
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Table 2.0729: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Tiredness) by Every 4 Weeks

Double-Blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Tiredness Symptom Score at Week 12			
Subjects Evaluable at Week 12, n	83	93	176
Tiredness Score = 0 at baseline and Tiredness Score >0 or missing at Week 12	3 (3.6%)	1 (1.1%)	4 (2.3%)
Responder, n(%)	15 (18.1%)	24 (25.8%)	39 (22.2%)
95% Exact CI	0.1048, 0.2805	0.1729, 0.3592	0.1626, 0.2902
Proportion Difference - Stratified CMH Method (95% CI)	-0.09 (-0.21, 0.04)		
p-value	0.19		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.08 (-0.20, 0.05)		
p-value	0.22		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.08 (-0.22, 0.07)		
p-value	0.28		
Unadjusted Inverse Relative Risk (95% CI)	1.43 (0.80, 2.53)		
p-value [1]	0.22		
Unadjusted Inverse Odds Ratio (95% CI)	1.58 (0.76, 3.26)		
p-value [1]	0.22		
Unadjusted Absolute Risk Difference (95% CI)	-0.08 (-0.20, 0.04)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.48 (0.84, 2.61)		
p-value [2]	0.17		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

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Table 2.0729: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Tiredness) by Every 4 Weeks

Double-Blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	68 (81.9%)	69 (74.2%)	137 (77.8%)
Last participation date < Day 78 in DB Phase	10 (12.0%)	0	10 (5.7%)
Last participation date >= Day 78 and Tiredness Score at Week 12 not available	2 (2.4%)	4 (4.3%)	6 (3.4%)
>0% increase from baseline at Week 12	21 (25.3%)	23 (24.7%)	44 (25.0%)
<50% reduction from baseline at Week 12	53 (63.9%)	64 (68.8%)	117 (66.5%)
Return Rate (%)	86%	96%	91%
Number of Subjects in Risk	76	94	170
Return Rate in Risk (%)	97%	96%	96%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

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Table 2.0729: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Tiredness) by Every 4 Weeks

Double-Blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Tiredness Symptom Score at Week 16			
Subjects Evaluable at Week 16, n	84	93	177
Tiredness Score = 0 at baseline and Tiredness Score >0 or missing at Week 16	4 (4.8%)	1 (1.1%)	5 (2.8%)
Responder, n(%)	14 (16.7%)	21 (22.6%)	35 (19.8%)
95% Exact CI	0.0942, 0.2638	0.1455, 0.3242	0.1418, 0.2641
Proportion Difference - Stratified CMH Method (95% CI)	-0.07 (-0.19, 0.06)		
p-value	0.30		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.06 (-0.18, 0.06)		
p-value	0.33		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.06 (-0.21, 0.09)		
p-value	0.35		
Unadjusted Inverse Relative Risk (95% CI)	1.35 (0.74, 2.49)		
p-value [1]	0.33		
Unadjusted Inverse Odds Ratio (95% CI)	1.46 (0.69, 3.09)		
p-value [1]	0.33		
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.18, 0.06)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.40 (0.77, 2.53)		
p-value [2]	0.27		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

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Table 2.0729: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Tiredness) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	70 (83.3%)	72 (77.4%)	142 (80.2%)
Last participation date < Day 106 in DB Phase	11 (13.1%)	4 (4.3%)	15 (8.5%)
Last participation date >= Day 106 and Tiredness Score at Week 16 not available	2 (2.4%)	4 (4.3%)	6 (3.4%)
>0% increase from baseline at Week 16	24 (28.6%)	26 (28.0%)	50 (28.2%)
<50% reduction from baseline at Week 16	53 (63.1%)	63 (67.7%)	116 (65.5%)
Return Rate (%)	85%	91%	88%
Number of Subjects in Risk	75	90	165
Return Rate in Risk (%)	97%	96%	96%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tss24-indv-gba.sas V.03.05 Output file: t-tss24-01-gba.pdf 29AUG2023: 9:46

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Table 2.0729: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Tiredness) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Tiredness Symptom Score at Week 20			
Subjects Evaluable at Week 20, n	83	93	176
Tiredness Score = 0 at baseline and Tiredness Score >0 or missing at Week 20	3 (3.6%)	1 (1.1%)	4 (2.3%)
Responder, n(%)	11 (13.3%)	23 (24.7%)	34 (19.3%)
95% Exact CI	0.0681, 0.2248	0.1637, 0.3476	0.1376, 0.2593
Proportion Difference - Stratified CMH Method (95% CI)	-0.12 (-0.24, 0.01)		
p-value	0.060		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.11 (-0.23, 0.00)		
p-value	0.052		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.11 (-0.26, 0.03)		
p-value	0.059		
Unadjusted Inverse Relative Risk (95% CI)	1.87 (0.97, 3.59)		
p-value [1]	0.062		
Unadjusted Inverse Odds Ratio (95% CI)	2.15 (0.98, 4.74)		
p-value [1]	0.058		
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.23, 0.00)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.90 (0.99, 3.65)		
p-value [2]	0.055		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 01JUL2019

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Table 2.0729: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Tiredness) by Every 4 Weeks

Double-Blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	72 (86.7%)	70 (75.3%)	142 (80.7%)
Last participation date < Day 134 in DB Phase	11 (13.3%)	4 (4.3%)	15 (8.5%)
Last participation date >= Day 134 and Tiredness Score at Week 20 not available	3 (3.6%)	3 (3.2%)	6 (3.4%)
>0% increase from baseline at Week 20	22 (26.5%)	26 (28.0%)	48 (27.3%)
<50% reduction from baseline at Week 20	55 (66.3%)	62 (66.7%)	117 (66.5%)
Return Rate (%)	84%	93%	88%
Number of Subjects in Risk	75	90	165
Return Rate in Risk (%)	96%	97%	96%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

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Table 2.0729: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Tiredness) by Every 4 Weeks
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Response Rate of Tiredness Symptom Score at Week 24			
Subjects Evaluable at Week 24, n	82	93	175
Tiredness Score = 0 at baseline and Tiredness Score >0 or missing at Week 24	2 (2.4%)	1 (1.1%)	3 (1.7%)
Responder, n(%)	14 (17.1%)	26 (28.0%)	40 (22.9%)
95% Exact CI	0.0966, 0.2698	0.1914, 0.3822	0.1686, 0.2980
Proportion Difference - Stratified CMH Method (95% CI)	-0.11 (-0.23, 0.02)		
p-value	0.11		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.11 (-0.23, 0.01)		
p-value	0.085		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.11 (-0.25, 0.04)		
p-value	0.11		
Unadjusted Inverse Relative Risk (95% CI)	1.64 (0.92, 2.92)		
p-value [1]	0.094		
Unadjusted Inverse Odds Ratio (95% CI)	1.88 (0.91, 3.92)		
p-value [1]	0.090		
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.23, 0.01)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.61 (0.91, 2.86)		
p-value [2]	0.10		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 01JUL2019

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Table 2.0729: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Tiredness) by Every 4 Weeks

Double-Blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Non-Responder, n(%)	68 (82.9%)	67 (72.0%)	135 (77.1%)
Last participation date < Day 162 in DB Phase	16 (19.5%)	8 (8.6%)	24 (13.7%)
Last participation date >= Day 162 and Tiredness Score at Week 24 not available	3 (3.7%)	6 (6.5%)	9 (5.1%)
>0% increase from baseline at Week 24	20 (24.4%)	23 (24.7%)	43 (24.6%)
<50% reduction from baseline at Week 24	47 (57.3%)	52 (55.9%)	99 (56.6%)
Return Rate (%)	78%	85%	82%
Number of Subjects in Risk	70	86	156
Return Rate in Risk (%)	96%	93%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

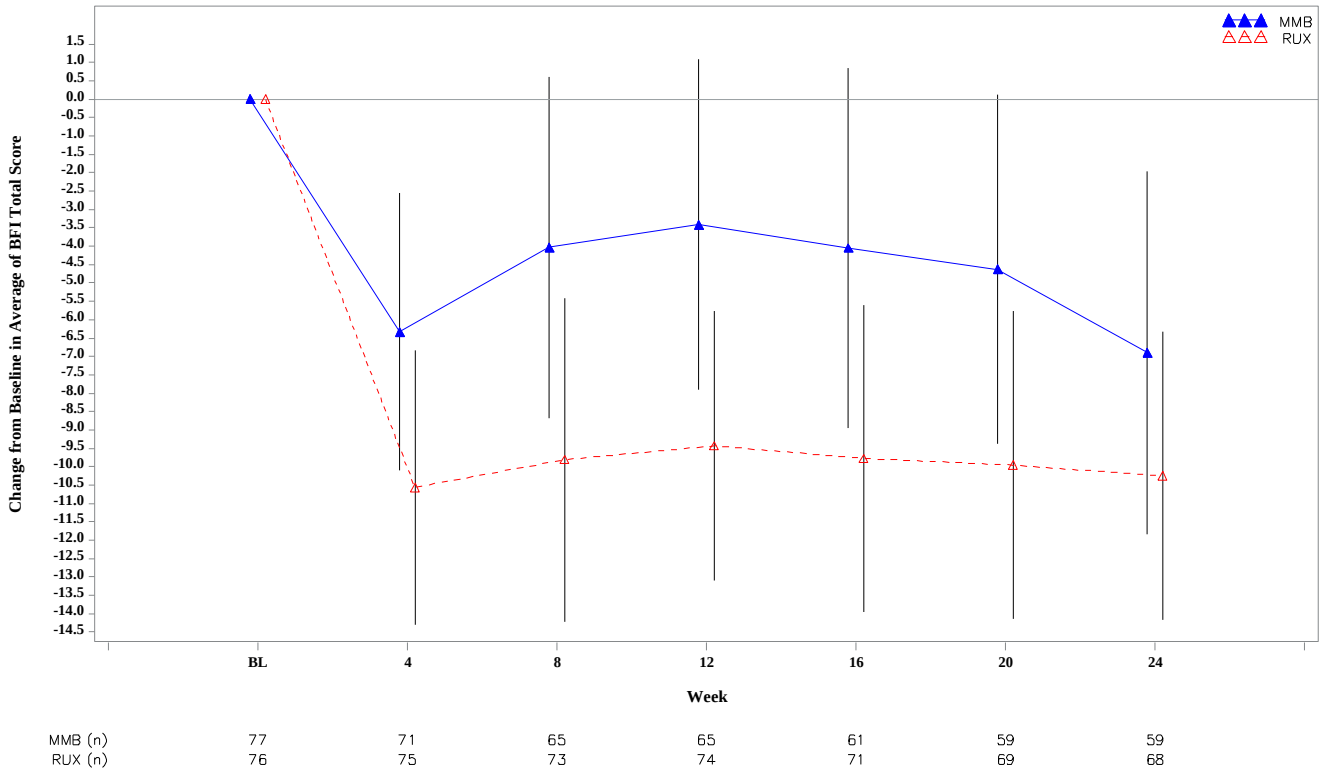
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

1.5 Fatigue

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Figure 2.6401.01: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Brief Total Inventory Score Over Time
Double-Blind Phase
ITT-Anemic Analysis Set

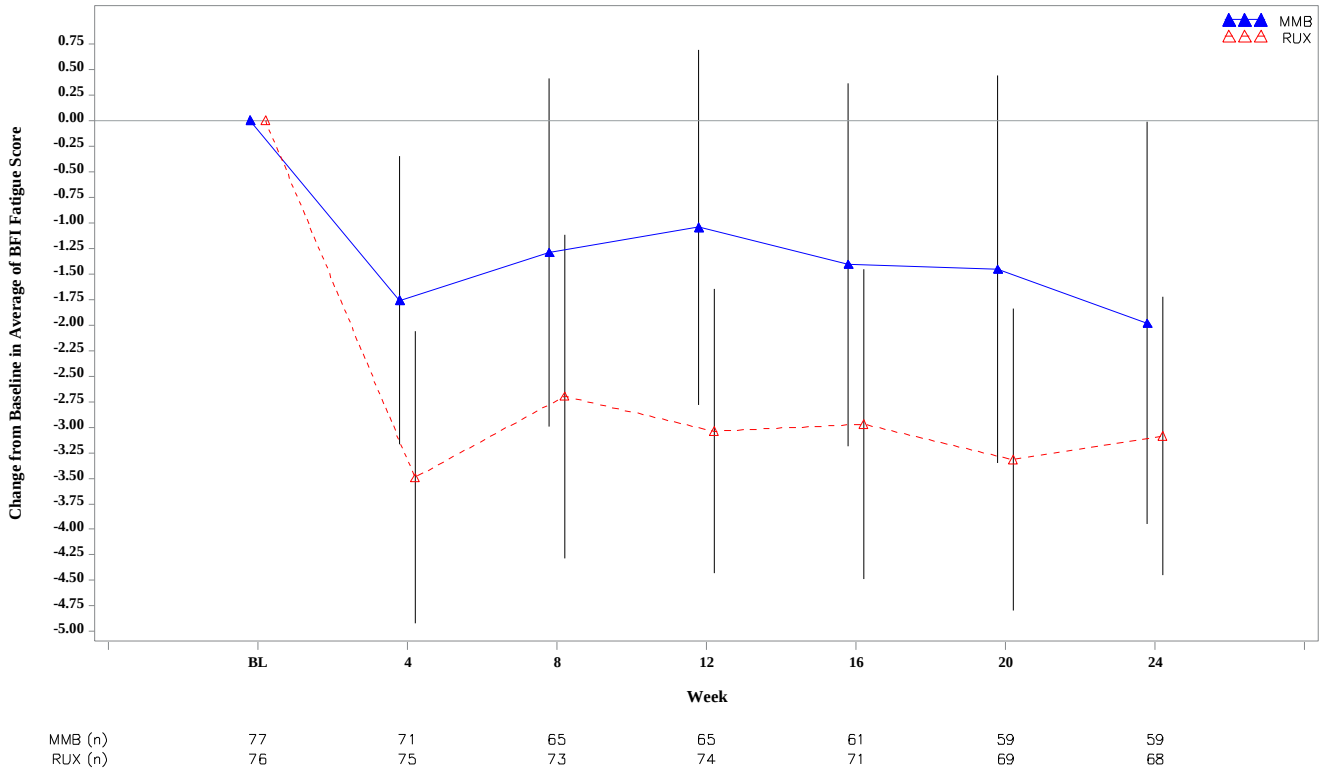


MMB (n)	77	71	65	65	61	59	59
RUX (n)	76	75	73	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line_adhoc.sas V.03.05 Output file: g-bfi-line-chg-rt.pdf 25JAN2024:11:51

Figure 2.6401.02: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Brief Fatigue Inventory Score Over Time
Double-Blind Phase
ITT-Anemic Analysis Set

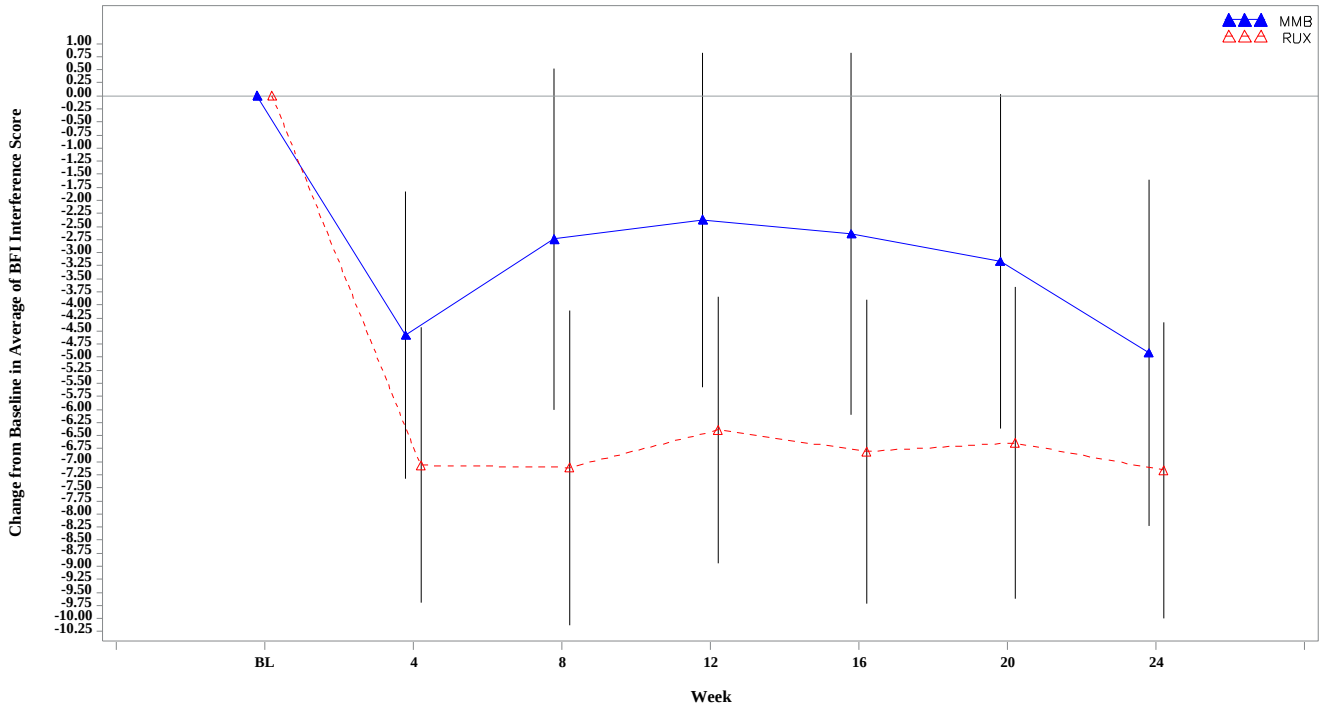


MMB (n)	77	71	65	65	61	59	59
RUX (n)	76	75	73	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line_adhoc.sas V.03.05 Output file: g-bfif-line-chg-rt.pdf 25JAN2024:11:49

Figure 2.6401.03: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Brief Interference Inventory Score Over Time
Double-Blind Phase
ITT-Anemic Analysis Set



MMB (n)	77	71	65	65	61	59	59
RUX (n)	76	75	73	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 01JUL2019
Source: g-spv-line_adhoc.sas V.03.05 Output file: g-bfii-line-chg-rt.pdf 25JAN2024:11:50

Table 2.6401.01: Analysis of Brief Total Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
BFISCORE - BFI Total Score at Baseline		
n	77	76
Mean (SD)	36.2 (23.32)	36.2 (22.54)
Median	35.0	34.5
Q1, Q3	19.0, 49.0	16.5, 52.0
Min, Max	0.0, 84.0	0.0, 79.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
BFISCORE - BFI Total Score at Week 4		
n	76	90
Mean (SD)	29.3 (21.12)	26.3 (21.16)
Median	24.0	23.0
Q1, Q3	14.0, 43.0	9.0, 41.0
Min, Max	0.0, 88.0	0.0, 85.0
Return Rate (%)	88%	96%
Number of Subjects in Risk	82	94
Return Rate in Risk (%)	93%	96%
Change in BFI Total Score at Week 4 from Baseline		
n	71	75
Mean (SD)	-6.3 (15.94)	-10.6 (16.23)
Median	-7.0	-8.0
Q1, Q3	-17.0, 4.0	-23.0, -1.0
Min, Max	-41.0, 30.0	-52.0, 30.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-bfi-gba_adhoc.sas V.03.05 Output file: t-chg-bfi-rt.pdf 25JAN2024:11:17

Table 2.6401.01: Analysis of Brief Total Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Change from Baseline at Week 4		
n [1]	73	76
n [2]	71	75
MMRM: Least Squares Mean [SE] (95% CI)	-2.62 [1.94] (-6.45, 1.20)	-7.46 [1.85] (-11.12, -3.81)
MMRM: Least Squares Mean Difference [SE] (95% CI)	4.84 [2.38] (0.13, 9.55)	
MMRM: P-value	0.044	
Corrected Hedges' g (95% CI)	0.298 (-0.028, 0.624)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.095	
Percent Change in BFI Total Score at Week 4 from Baseline		
n	68	74
Mean (SD)	5.2 (128.72)	-28.9 (44.37)
Median	-21.1	-30.0
Q1, Q3	-48.6, 11.7	-62.0, -5.2
Min, Max	-100.0, 900.0	-100.0, 109.5
Difference in Percent Change from Baseline at Week 4		
n [1]	70	75
n [2]	68	74
MMRM: Least Squares Mean [SE] (95% CI)	10.77 [11.99] (-12.93, 34.47)	-23.37 [11.42] (-45.94, -0.79)
MMRM: Least Squares Mean Difference [SE] (95% CI)	34.14 [15.87] (2.76, 65.51)	
MMRM: P-value	0.033	
Corrected Hedges' g (95% CI)	0.345 (0.013, 0.676)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.061	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-bfi-gba_adhoc.sas V.03.05 Output file: t-chg-bfi-rt.pdf 25JAN2024:11:17

Table 2.6401.01: Analysis of Brief Total Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
BFISCORE - BFI Total Score at Week 8			
n	70	86	
Mean (SD)	31.2 (21.81)	26.1 (21.15)	
Median	25.5	21.5	
Q1, Q3	13.0, 49.0	8.0, 39.0	
Min, Max	0.0, 81.0	0.0, 74.0	
Return Rate (%)	81%	91%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	91%	
Change in BFI Total Score at Week 8 from Baseline			
n	65	73	
Mean (SD)	-4.0 (18.75)	-9.8 (18.88)	
Median	-6.0	-8.0	
Q1, Q3	-17.0, 10.0	-18.0, 0.0	
Min, Max	-45.0, 62.0	-73.0, 36.0	
Difference in Change from Baseline at Week 8			
n [1]	73	76	
n [2]	65	73	
MMRM: Least Squares Mean [SE] (95% CI)	0.59 [2.27] (-3.89, 5.08)	-7.20 [2.15] (-11.46, -2.95)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	7.80 [2.88] (2.11, 13.49)		
MMRM: P-value	0.008		
Corrected Hedges' g (95% CI)	0.423 (0.085, 0.761)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.13		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-bfi-gba_adhoc.sas V.03.05 Output file: t-chg-bfi-rt.pdf 25JAN2024:11:17

Table 2.6401.01: Analysis of Brief Total Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in BFI Total Score at Week 8 from Baseline		
n	62	72
Mean (SD)	20.5 (279.98)	-18.6 (73.55)
Median	-28.1	-29.8
Q1, Q3	-51.4, 23.8	-66.7, 0.3
Min, Max	-100.0, 2150.0	-100.0, 300.0
Difference in Percent Change from Baseline at Week 8		
n [1]	70	75
n [2]	62	72
MMRM: Least Squares Mean [SE] (95% CI)	28.17 [25.54] (-22.34, 78.68)	-14.47 [23.97] (-61.88, 32.93)
MMRM: Least Squares Mean Difference [SE] (95% CI)	42.65 [34.71] (-26.00, 111.29)	
MMRM: P-value	0.22	
Corrected Hedges' g (95% CI)	0.210 (-0.131, 0.550)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.10	
BFISCORE - BFI Total Score at Week 12		
n	71	89
Mean (SD)	30.2 (20.29)	26.5 (20.54)
Median	28.0	24.0
Q1, Q3	14.0, 42.0	8.0, 39.0
Min, Max	0.0, 83.0	0.0, 84.0
Return Rate (%)	83%	95%
Number of Subjects in Risk	76	94
Return Rate in Risk (%)	93%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-bfi-gba_adhoc.sas V.03.05 Output file: t-chg-bfi-rt.pdf 25JAN2024:11:17

Table 2.6401.01: Analysis of Brief Total Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Change in BFI Total Score at Week 12 from Baseline		
n	65	74
Mean (SD)	-3.4 (18.15)	-9.4 (15.86)
Median	-2.0	-7.5
Q1, Q3	-14.0, 7.0	-15.0, 0.0
Min, Max	-47.0, 40.0	-63.0, 22.0
Difference in Change from Baseline at Week 12		
n [1]	73	76
n [2]	65	74
MMRM: Least Squares Mean [SE] (95% CI)	0.51 [2.02] (-3.50, 4.51)	-6.00 [1.90] (-9.76, -2.24)
MMRM: Least Squares Mean Difference [SE] (95% CI)	6.50 [2.49] (1.57, 11.43)	
MMRM: P-value	0.010	
Corrected Hedges' g (95% CI)	0.396 (0.059, 0.732)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.026	
Percent Change in BFI Total Score at Week 12 from Baseline		
n	62	73
Mean (SD)	56.3 (386.37)	-22.0 (54.13)
Median	-15.4	-28.3
Q1, Q3	-47.1, 26.7	-60.0, 0.0
Min, Max	-100.0, 2900.0	-100.0, 200.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-bfi-gba_adhoc.sas V.03.05 Output file: t-chg-bfi-rt.pdf 25JAN2024:11:17

Table 2.6401.01: Analysis of Brief Total Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Percent Change from Baseline at Week 12		
n [1]	70	75
n [2]	62	73
MMRM: Least Squares Mean [SE] (95% CI)	65.62 [33.01] (0.35, 130.89)	-13.87 [31.29] (-75.75, 48.00)
MMRM: Least Squares Mean Difference [SE] (95% CI)	79.49 [45.23] (-9.94, 168.92)	
MMRM: P-value	0.081	
Corrected Hedges' g (95% CI)	0.299 (-0.041, 0.640)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.042	
BFISCORE - BFI Total Score at Week 16		
n	67	83
Mean (SD)	30.5 (22.48)	26.1 (21.17)
Median	31.0	25.0
Q1, Q3	12.0, 50.0	8.0, 38.0
Min, Max	0.0, 90.0	0.0, 80.0
Return Rate (%)	78%	88%
Number of Subjects in Risk	75	91
Return Rate in Risk (%)	89%	91%
Change in BFI Total Score at Week 16 from Baseline		
n	61	71
Mean (SD)	-4.0 (19.10)	-9.8 (17.61)
Median	-5.0	-6.0
Q1, Q3	-13.0, 8.0	-22.0, 1.0
Min, Max	-58.0, 48.0	-73.0, 20.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.6401.01: Analysis of Brief Total Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	73	76	
n [2]	61	71	
MMRM: Least Squares Mean [SE] (95% CI)	0.80 [2.26] (-3.68, 5.28)	-6.35 [2.13] (-10.56, -2.15)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	7.15 [2.86] (1.51, 12.80)		
MMRM: P-value	0.013		
Corrected Hedges' g (95% CI)	0.399 (0.054, 0.745)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.19		
Percent Change in BFI Total Score at Week 16 from Baseline			
n	59	70	
Mean (SD)	28.6 (319.50)	-26.8 (47.70)	
Median	-18.0	-30.2	
Q1, Q3	-54.4, 25.0	-60.0, 1.3	
Min, Max	-100.0, 2400.0	-100.0, 100.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	70	75	
n [2]	59	70	
MMRM: Least Squares Mean [SE] (95% CI)	33.70 [27.93] (-21.52, 88.92)	-20.59 [26.18] (-72.36, 31.18)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	54.29 [37.98] (-20.82, 129.40)		
MMRM: P-value	0.16		
Corrected Hedges' g (95% CI)	0.249 (-0.099, 0.596)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.15		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-bfi-gba_adhoc.sas V.03.05 Output file: t-chg-bfi-rt.pdf 25JAN2024:11:17

Table 2.6401.01: Analysis of Brief Total Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
BFISCORE - BFI Total Score at Week 20		
n	64	83
Mean (SD)	30.2 (23.43)	25.5 (21.08)
Median	25.5	23.0
Q1, Q3	11.0, 41.5	8.0, 37.0
Min, Max	0.0, 90.0	0.0, 83.0
Return Rate (%)	74%	88%
Number of Subjects in Risk	74	90
Return Rate in Risk (%)	86%	92%
Change in BFI Total Score at Week 20 from Baseline		
n	59	69
Mean (SD)	-4.6 (18.19)	-10.0 (17.43)
Median	-5.0	-7.0
Q1, Q3	-16.0, 10.0	-19.0, 0.0
Min, Max	-63.0, 41.0	-70.0, 24.0
Difference in Change from Baseline at Week 20		
n [1]	73	76
n [2]	59	69
MMRM: Least Squares Mean [SE] (95% CI)	0.98 [2.25] (-3.47, 5.42)	-6.80 [2.10] (-10.96, -2.65)
MMRM: Least Squares Mean Difference [SE] (95% CI)	7.78 [2.83] (2.19, 13.37)	
MMRM: P-value	0.007	
Corrected Hedges' g (95% CI)	0.445 (0.093, 0.797)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.18	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-bfi-gba_adhoc.sas V.03.05 Output file: t-chg-bfi-rt.pdf 25JAN2024:11:17

Table 2.6401.01: Analysis of Brief Total Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in BFI Total Score at Week 20 from Baseline		
n	58	68
Mean (SD)	1.9 (118.81)	-28.6 (42.40)
Median	-21.4	-29.9
Q1, Q3	-54.1, 21.3	-56.7, -1.1
Min, Max	-100.0, 750.0	-100.0, 100.0
Difference in Percent Change from Baseline at Week 20		
n [1]	70	75
n [2]	58	68
MMRM: Least Squares Mean [SE] (95% CI)	11.17 [11.43] (-11.43, 33.76)	-23.59 [10.67] (-44.68, -2.50)
MMRM: Least Squares Mean Difference [SE] (95% CI)	34.75 [14.91] (5.28, 64.23)	
MMRM: P-value	0.021	
Corrected Hedges' g (95% CI)	0.395 (0.041, 0.748)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.17	
BFISCORE - BFI Total Score at Week 24		
n	65	82
Mean (SD)	26.5 (19.73)	23.6 (20.30)
Median	23.0	20.0
Q1, Q3	12.0, 35.0	9.0, 34.0
Min, Max	0.0, 87.0	0.0, 90.0
Return Rate (%)	76%	87%
Number of Subjects in Risk	70	87
Return Rate in Risk (%)	93%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-bfi-gba_adhoc.sas V.03.05 Output file: t-chg-bfi-rt.pdf 25JAN2024:11:17

Table 2.6401.01: Analysis of Brief Total Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Change in BFI Total Score at Week 24 from Baseline		
n	59	68
Mean (SD)	-6.9 (18.98)	-10.3 (16.19)
Median	-4.0	-8.0
Q1, Q3	-20.0, 5.0	-21.0, -1.0
Min, Max	-63.0, 56.0	-69.0, 28.0
Difference in Change from Baseline at Week 24		
n [1]	73	76
n [2]	59	68
MMRM: Least Squares Mean [SE] (95% CI)	-1.77 [2.12] (-5.96, 2.42)	-7.21 [1.99] (-11.16, -3.27)
MMRM: Least Squares Mean Difference [SE] (95% CI)	5.44 [2.64] (0.22, 10.67)	
MMRM: P-value	0.041	
Corrected Hedges' g (95% CI)	0.330 (-0.021, 0.682)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.24	
Percent Change in BFI Total Score at Week 24 from Baseline		
n	57	67
Mean (SD)	100.5 (752.08)	-30.2 (51.03)
Median	-23.1	-34.6
Q1, Q3	-52.9, 17.9	-70.0, -3.3
Min, Max	-100.0, 5600.0	-100.0, 164.7

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-bfi-gba_adhoc.sas V.03.05 Output file: t-chg-bfi-rt.pdf 25JAN2024:11:17

Table 2.6401.01: Analysis of Brief Total Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Percent Change from Baseline at Week 24		
n [1]	70	75
n [2]	57	67
MMRM: Least Squares Mean [SE] (95% CI)	114.43 [62.77] (-9.69, 238.54)	-20.42 [59.41] (-137.91, 97.07)
MMRM: Least Squares Mean Difference [SE] (95% CI)	134.85 [86.28] (-35.77, 305.47)	
MMRM: P-value	0.12	
Corrected Hedges' g (95% CI)	0.279 (-0.076, 0.634)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.13	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-bfi-gba_adhoc.sas V.03.05 Output file: t-chg-bfi-rt.pdf 25JAN2024:11:17

Table 2.6401.02: Analysis of Brief Fatigue Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
BFIFATIG - BFI Fatigue Score at Baseline		
n	77	76
Mean (SD)	13.2 (7.67)	13.3 (7.34)
Median	14.0	13.5
Q1, Q3	8.0, 17.0	6.0, 20.0
Min, Max	0.0, 30.0	0.0, 27.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
BFIFATIG - BFI Fatigue Score at Week 4		
n	76	90
Mean (SD)	11.2 (7.33)	10.0 (7.54)
Median	10.0	10.0
Q1, Q3	6.0, 16.0	4.0, 14.0
Min, Max	0.0, 30.0	0.0, 30.0
Return Rate (%)	88%	96%
Number of Subjects in Risk	82	94
Return Rate in Risk (%)	93%	96%
Change in BFI Fatigue Score at Week 4 from Baseline		
n	71	75
Mean (SD)	-1.8 (5.97)	-3.5 (6.20)
Median	-1.0	-3.0
Q1, Q3	-6.0, 2.0	-8.0, 0.0
Min, Max	-20.0, 11.0	-16.0, 16.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-bfi-gba_adhoc.sas V.03.05 Output file: t-chg-bfif-rt.pdf 25JAN2024:11:17

Table 2.6401.02: Analysis of Brief Fatigue Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Change from Baseline at Week 4		
n [1]	73	76
n [2]	71	75
MMRM: Least Squares Mean [SE] (95% CI)	-0.38 [0.77] (-1.89, 1.13)	-2.32 [0.73] (-3.77, -0.88)
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.94 [0.93] (0.09, 3.79)	
MMRM: P-value	0.040	
Corrected Hedges' g (95% CI)	0.303 (-0.024, 0.629)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.031	
Percent Change in BFI Fatigue Score at Week 4 from Baseline		
n	67	74
Mean (SD)	-5.5 (61.71)	-22.2 (61.30)
Median	-11.5	-31.9
Q1, Q3	-50.0, 21.4	-53.8, 0.0
Min, Max	-100.0, 200.0	-100.0, 300.0
Difference in Percent Change from Baseline at Week 4		
n [1]	68	75
n [2]	67	74
MMRM: Least Squares Mean [SE] (95% CI)	4.23 [8.17] (-11.93, 20.39)	-14.44 [7.68] (-29.64, 0.75)
MMRM: Least Squares Mean Difference [SE] (95% CI)	18.67 [10.33] (-1.76, 39.11)	
MMRM: P-value	0.073	
Corrected Hedges' g (95% CI)	0.279 (-0.053, 0.612)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.018	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.6401.02: Analysis of Brief Fatigue Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
BFIFATIG - BFI Fatigue Score at Week 8		
n	70	86
Mean (SD)	11.7 (7.15)	10.3 (7.62)
Median	10.0	9.0
Q1, Q3	6.0, 17.0	4.0, 16.0
Min, Max	0.0, 30.0	0.0, 28.0
Return Rate (%)	81%	91%
Number of Subjects in Risk	79	94
Return Rate in Risk (%)	89%	91%
Change in BFI Fatigue Score at Week 8 from Baseline		
n	65	73
Mean (SD)	-1.3 (6.88)	-2.7 (6.78)
Median	-2.0	-3.0
Q1, Q3	-6.0, 3.0	-6.0, 2.0
Min, Max	-18.0, 20.0	-20.0, 13.0
Difference in Change from Baseline at Week 8		
n [1]	73	76
n [2]	65	73
MMRM: Least Squares Mean [SE] (95% CI)	0.35 [0.85] (-1.33, 2.03)	-1.86 [0.81] (-3.45, -0.26)
MMRM: Least Squares Mean Difference [SE] (95% CI)	2.21 [1.06] (0.11, 4.31)	
MMRM: P-value	0.039	
Corrected Hedges' g (95% CI)	0.319 (-0.017, 0.656)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.34	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.6401.02: Analysis of Brief Fatigue Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in BFI Fatigue Score at Week 8 from Baseline		
n	62	72
Mean (SD)	8.3 (161.77)	-9.2 (91.00)
Median	-18.3	-25.2
Q1, Q3	-45.0, 15.4	-51.5, 13.8
Min, Max	-100.0, 1200.0	-100.0, 600.0
Difference in Percent Change from Baseline at Week 8		
n [1]	68	75
n [2]	62	72
MMRM: Least Squares Mean [SE] (95% CI)	16.78 [15.90] (-14.66, 48.23)	-3.98 [14.79] (-33.23, 25.28)
MMRM: Least Squares Mean Difference [SE] (95% CI)	20.76 [21.27] (-21.31, 62.83)	
MMRM: P-value	0.33	
Corrected Hedges' g (95% CI)	0.165 (-0.175, 0.505)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.30	
BFIFATIG - BFI Fatigue Score at Week 12		
n	71	89
Mean (SD)	11.4 (6.85)	10.2 (7.19)
Median	10.0	9.0
Q1, Q3	6.0, 15.0	5.0, 15.0
Min, Max	0.0, 30.0	0.0, 29.0
Return Rate (%)	83%	95%
Number of Subjects in Risk	76	94
Return Rate in Risk (%)	93%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.6401.02: Analysis of Brief Fatigue Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Change in BFI Fatigue Score at Week 12 from Baseline		
n	65	74
Mean (SD)	-1.0 (7.00)	-3.0 (6.00)
Median	-1.0	-2.0
Q1, Q3	-5.0, 3.0	-7.0, 1.0
Min, Max	-18.0, 14.0	-20.0, 11.0
Difference in Change from Baseline at Week 12		
n [1]	73	76
n [2]	65	74
MMRM: Least Squares Mean [SE] (95% CI)	0.41 [0.78] (-1.13, 1.95)	-1.69 [0.73] (-3.14, -0.24)
MMRM: Least Squares Mean Difference [SE] (95% CI)	2.10 [0.95] (0.23, 3.98)	
MMRM: P-value	0.028	
Corrected Hedges' g (95% CI)	0.332 (-0.004, 0.667)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.038	
Percent Change in BFI Fatigue Score at Week 12 from Baseline		
n	61	73
Mean (SD)	9.1 (120.57)	-17.6 (55.97)
Median	-16.7	-22.2
Q1, Q3	-48.3, 25.0	-50.0, 8.3
Min, Max	-100.0, 800.0	-100.0, 300.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.6401.02: Analysis of Brief Fatigue Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Percent Change from Baseline at Week 12		
n [1]	68	75
n [2]	61	73
MMRM: Least Squares Mean [SE] (95% CI)	18.71 [11.43] (-3.89, 41.31)	-8.97 [10.54] (-29.82, 11.89)
MMRM: Least Squares Mean Difference [SE] (95% CI)	27.67 [14.93] (-1.84, 57.19)	
MMRM: P-value	0.066	
Corrected Hedges' g (95% CI)	0.307 (-0.035, 0.649)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.18	
BFIFATIG - BFI Fatigue Score at Week 16		
n	67	83
Mean (SD)	11.4 (7.52)	10.3 (7.57)
Median	10.0	10.0
Q1, Q3	6.0, 17.0	3.0, 14.0
Min, Max	0.0, 30.0	0.0, 28.0
Return Rate (%)	78%	88%
Number of Subjects in Risk	75	91
Return Rate in Risk (%)	89%	91%
Change in BFI Fatigue Score at Week 16 from Baseline		
n	61	71
Mean (SD)	-1.4 (6.93)	-3.0 (6.40)
Median	-1.0	-2.0
Q1, Q3	-6.0, 3.0	-6.0, 2.0
Min, Max	-21.0, 17.0	-21.0, 9.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.6401.02: Analysis of Brief Fatigue Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Change from Baseline at Week 16		
n [1]	73	76
n [2]	61	71
MMRM: Least Squares Mean [SE] (95% CI)	0.50 [0.85] (-1.17, 2.17)	-1.73 [0.79] (-3.30, -0.16)
MMRM: Least Squares Mean Difference [SE] (95% CI)	2.22 [1.05] (0.15, 4.30)	
MMRM: P-value	0.036	
Corrected Hedges' g (95% CI)	0.332 (-0.012, 0.677)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.20	
Percent Change in BFI Fatigue Score at Week 16 from Baseline		
n	59	70
Mean (SD)	19.4 (228.88)	-15.2 (63.33)
Median	-11.1	-20.0
Q1, Q3	-50.0, 25.0	-52.9, 10.0
Min, Max	-100.0, 1700.0	-100.0, 250.0
Difference in Percent Change from Baseline at Week 16		
n [1]	68	75
n [2]	59	70
MMRM: Least Squares Mean [SE] (95% CI)	26.28 [19.70] (-12.69, 65.25)	-7.41 [18.23] (-43.47, 28.64)
MMRM: Least Squares Mean Difference [SE] (95% CI)	33.69 [26.48] (-18.69, 86.07)	
MMRM: P-value	0.21	
Corrected Hedges' g (95% CI)	0.220 (-0.127, 0.568)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.17	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.6401.02: Analysis of Brief Fatigue Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
BFIFATIG - BFI Fatigue Score at Week 20		
n	64	83
Mean (SD)	11.4 (7.85)	9.8 (6.93)
Median	10.0	9.0
Q1, Q3	6.0, 16.0	4.0, 14.0
Min, Max	0.0, 30.0	0.0, 28.0
Return Rate (%)	74%	88%
Number of Subjects in Risk	74	90
Return Rate in Risk (%)	86%	92%
Change in BFI Fatigue Score at Week 20 from Baseline		
n	59	69
Mean (SD)	-1.5 (7.26)	-3.3 (6.14)
Median	-1.0	-3.0
Q1, Q3	-6.0, 3.0	-6.0, 0.0
Min, Max	-21.0, 16.0	-21.0, 9.0
Difference in Change from Baseline at Week 20		
n [1]	73	76
n [2]	59	69
MMRM: Least Squares Mean [SE] (95% CI)	0.75 [0.85] (-0.93, 2.42)	-2.24 [0.79] (-3.81, -0.68)
MMRM: Least Squares Mean Difference [SE] (95% CI)	2.99 [1.05] (0.92, 5.07)	
MMRM: P-value	0.005	
Corrected Hedges' g (95% CI)	0.454 (0.102, 0.806)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.071	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.6401.02: Analysis of Brief Fatigue Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in BFI Fatigue Score at Week 20 from Baseline		
n	57	68
Mean (SD)	5.5 (111.83)	-21.5 (48.09)
Median	-13.3	-30.4
Q1, Q3	-50.0, 25.0	-50.0, 0.0
Min, Max	-100.0, 700.0	-100.0, 150.0
Difference in Percent Change from Baseline at Week 20		
n [1]	68	75
n [2]	57	68
MMRM: Least Squares Mean [SE] (95% CI)	15.23 [10.47] (-5.48, 35.95)	-15.35 [9.65] (-34.44, 3.75)
MMRM: Least Squares Mean Difference [SE] (95% CI)	30.58 [13.57] (3.75, 57.41)	
MMRM: P-value	0.026	
Corrected Hedges' g (95% CI)	0.383 (0.028, 0.738)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.090	
BFIFATIG - BFI Fatigue Score at Week 24		
n	65	82
Mean (SD)	10.3 (6.86)	9.5 (7.12)
Median	9.0	9.0
Q1, Q3	6.0, 13.0	4.0, 14.0
Min, Max	0.0, 30.0	0.0, 30.0
Return Rate (%)	76%	87%
Number of Subjects in Risk	70	87
Return Rate in Risk (%)	93%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.6401.02: Analysis of Brief Fatigue Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Change in BFI Fatigue Score at Week 24 from Baseline		
n	59	68
Mean (SD)	-2.0 (7.54)	-3.1 (5.63)
Median	-3.0	-3.0
Q1, Q3	-7.0, 3.0	-6.0, 0.0
Min, Max	-21.0, 25.0	-19.0, 11.0
Difference in Change from Baseline at Week 24		
n [1]	73	76
n [2]	59	68
MMRM: Least Squares Mean [SE] (95% CI)	0.12 [0.83] (-1.51, 1.75)	-1.85 [0.78] (-3.39, -0.32)
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.98 [1.02] (-0.04, 3.99)	
MMRM: P-value	0.054	
Corrected Hedges' g (95% CI)	0.309 (-0.042, 0.659)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.45	
Percent Change in BFI Fatigue Score at Week 24 from Baseline		
n	56	67
Mean (SD)	4.8 (111.45)	-24.1 (51.32)
Median	-25.0	-30.0
Q1, Q3	-50.0, 24.9	-60.0, 0.0
Min, Max	-100.0, 500.0	-100.0, 200.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.6401.02: Analysis of Brief Fatigue Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Percent Change from Baseline at Week 24		
n [1]	68	75
n [2]	56	67
MMRM: Least Squares Mean [SE] (95% CI)	14.56 [10.78] (-6.77, 35.89)	-16.50 [9.95] (-36.17, 3.18)
MMRM: Least Squares Mean Difference [SE] (95% CI)	31.06 [14.00] (3.37, 58.74)	
MMRM: P-value	0.028	
Corrected Hedges' g (95% CI)	0.381 (0.023, 0.739)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.11	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.6401.03: Analysis of Brief Interference Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
BFIINTER - BFI Interference Score at Baseline		
n	77	76
Mean (SD)	23.0 (16.39)	23.0 (15.90)
Median	21.0	23.0
Q1, Q3	10.0, 34.0	8.5, 32.5
Min, Max	0.0, 57.0	0.0, 55.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
BFIINTER - BFI Interference Score at Week 4		
n	76	90
Mean (SD)	18.1 (14.43)	16.3 (14.31)
Median	14.0	12.0
Q1, Q3	6.5, 28.0	4.0, 26.0
Min, Max	0.0, 58.0	0.0, 55.0
Return Rate (%)	88%	96%
Number of Subjects in Risk	82	94
Return Rate in Risk (%)	93%	96%
Change in BFI Interference Score at Week 4 from Baseline		
n	71	75
Mean (SD)	-4.6 (11.64)	-7.1 (11.44)
Median	-3.0	-6.0
Q1, Q3	-10.0, 3.0	-13.0, 1.0
Min, Max	-30.0, 21.0	-47.0, 14.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.6401.03: Analysis of Brief Interference Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Change from Baseline at Week 4		
n [1]	73	76
n [2]	71	75
MMRM: Least Squares Mean [SE] (95% CI)	-2.30 [1.34] (-4.94, 0.34)	-5.24 [1.28] (-7.76, -2.71)
MMRM: Least Squares Mean Difference [SE] (95% CI)	2.94 [1.65] (-0.32, 6.20)	
MMRM: P-value	0.077	
Corrected Hedges' g (95% CI)	0.262 (-0.064, 0.588)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.15	
Percent Change in BFI Interference Score at Week 4 from Baseline		
n	66	72
Mean (SD)	-1.6 (77.85)	-22.5 (81.44)
Median	-17.3	-36.3
Q1, Q3	-50.0, 19.4	-66.7, 3.6
Min, Max	-100.0, 300.0	-100.0, 500.0
Difference in Percent Change from Baseline at Week 4		
n [1]	68	73
n [2]	66	72
MMRM: Least Squares Mean [SE] (95% CI)	5.39 [10.69] (-15.75, 26.54)	-16.50 [10.01] (-36.30, 3.31)
MMRM: Least Squares Mean Difference [SE] (95% CI)	21.89 [13.25] (-4.32, 48.10)	
MMRM: P-value	0.10	
Corrected Hedges' g (95% CI)	0.254 (-0.082, 0.589)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.028	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.6401.03: Analysis of Brief Interference Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
BFIINTER - BFI Interference Score at Week 8		
n	70	86
Mean (SD)	19.5 (15.31)	15.8 (14.12)
Median	17.0	11.0
Q1, Q3	7.0, 32.0	3.0, 26.0
Min, Max	0.0, 53.0	0.0, 48.0
Return Rate (%)	81%	91%
Number of Subjects in Risk	79	94
Return Rate in Risk (%)	89%	91%
Change in BFI Interference Score at Week 8 from Baseline		
n	65	73
Mean (SD)	-2.7 (13.17)	-7.1 (12.90)
Median	-3.0	-5.0
Q1, Q3	-12.0, 5.0	-13.0, 0.0
Min, Max	-30.0, 42.0	-53.0, 23.0
Difference in Change from Baseline at Week 8		
n [1]	73	76
n [2]	65	73
MMRM: Least Squares Mean [SE] (95% CI)	0.05 [1.53] (-2.97, 3.06)	-5.42 [1.44] (-8.27, -2.57)
MMRM: Least Squares Mean Difference [SE] (95% CI)	5.47 [1.92] (1.67, 9.28)	
MMRM: P-value	0.005	
Corrected Hedges' g (95% CI)	0.442 (0.104, 0.781)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.10	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-bfi-gba_adhoc.sas V.03.05 Output file: t-chg-bfii-rt.pdf 25JAN2024:11:18

Table 2.6401.03: Analysis of Brief Interference Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in BFI Interference Score at Week 8 from Baseline		
n	60	70
Mean (SD)	41.6 (408.70)	-9.6 (128.22)
Median	-24.3	-35.9
Q1, Q3	-57.6, 9.3	-78.4, 0.0
Min, Max	-100.0, 3100.0	-100.0, 700.0
Difference in Percent Change from Baseline at Week 8		
n [1]	68	73
n [2]	60	70
MMRM: Least Squares Mean [SE] (95% CI)	106.50 [57.09] (-6.42, 219.42)	-6.22 [53.50] (-112.04, 99.60)
MMRM: Least Squares Mean Difference [SE] (95% CI)	112.72 [77.99] (-41.53, 266.97)	
MMRM: P-value	0.15	
Corrected Hedges' g (95% CI)	0.252 (-0.094, 0.598)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.065	
BFIINTER - BFI Interference Score at Week 12		
n	71	89
Mean (SD)	18.8 (14.02)	16.3 (14.07)
Median	16.0	14.0
Q1, Q3	8.0, 25.0	4.0, 28.0
Min, Max	0.0, 55.0	0.0, 55.0
Return Rate (%)	83%	95%
Number of Subjects in Risk	76	94
Return Rate in Risk (%)	93%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-bfi-gba_adhoc.sas V.03.05 Output file: t-chg-bfii-rt.pdf 25JAN2024:11:18

Table 2.6401.03: Analysis of Brief Interference Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Change in BFI Interference Score at Week 12 from Baseline		
n	65	74
Mean (SD)	-2.4 (12.92)	-6.4 (11.00)
Median	-1.0	-5.0
Q1, Q3	-11.0, 4.0	-10.0, 0.0
Min, Max	-31.0, 40.0	-43.0, 15.0
Difference in Change from Baseline at Week 12		
n [1]	73	76
n [2]	65	74
MMRM: Least Squares Mean [SE] (95% CI)	0.00 [1.39] (-2.76, 2.75)	-4.38 [1.31] (-6.97, -1.80)
MMRM: Least Squares Mean Difference [SE] (95% CI)	4.38 [1.72] (0.98, 7.77)	
MMRM: P-value	0.012	
Corrected Hedges' g (95% CI)	0.388 (0.051, 0.724)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.047	
Percent Change in BFI Interference Score at Week 12 from Baseline		
n	60	71
Mean (SD)	49.3 (236.99)	-20.8 (85.81)
Median	-14.0	-30.8
Q1, Q3	-41.1, 33.3	-70.4, 0.0
Min, Max	-100.0, 1500.0	-100.0, 400.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-bfi-gba_adhoc.sas V.03.05 Output file: t-chg-bfii-rt.pdf 25JAN2024:11:18

Table 2.6401.03: Analysis of Brief Interference Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Percent Change from Baseline at Week 12		
n [1]	68	73
n [2]	60	71
MMRM: Least Squares Mean [SE] (95% CI)	51.60 [21.52] (9.04, 94.17)	-14.16 [19.99] (-53.70, 25.39)
MMRM: Least Squares Mean Difference [SE] (95% CI)	65.76 [28.70] (8.99, 122.54)	
MMRM: P-value	0.024	
Corrected Hedges' g (95% CI)	0.390 (0.043, 0.737)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.008	
BFIINTER - BFI Interference Score at Week 16		
n	67	83
Mean (SD)	19.1 (15.37)	15.7 (14.34)
Median	18.0	14.0
Q1, Q3	4.0, 31.0	2.0, 26.0
Min, Max	0.0, 60.0	0.0, 53.0
Return Rate (%)	78%	88%
Number of Subjects in Risk	75	91
Return Rate in Risk (%)	89%	91%
Change in BFI Interference Score at Week 16 from Baseline		
n	61	71
Mean (SD)	-2.6 (13.54)	-6.8 (12.29)
Median	-3.0	-5.0
Q1, Q3	-10.0, 5.0	-14.0, 0.0
Min, Max	-40.0, 38.0	-52.0, 18.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-bfi-gba_adhoc.sas V.03.05 Output file: t-chg-bfii-rt.pdf 25JAN2024:11:18

Table 2.6401.03: Analysis of Brief Interference Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Change from Baseline at Week 16		
n [1]	73	76
n [2]	61	71
MMRM: Least Squares Mean [SE] (95% CI)	0.15 [1.54] (-2.89, 3.20)	-4.71 [1.44] (-7.57, -1.86)
MMRM: Least Squares Mean Difference [SE] (95% CI)	4.87 [1.94] (1.03, 8.70)	
MMRM: P-value	0.013	
Corrected Hedges' g (95% CI)	0.400 (0.054, 0.745)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.093	
Percent Change in BFI Interference Score at Week 16 from Baseline		
n	57	68
Mean (SD)	49.1 (419.54)	-25.0 (76.65)
Median	-22.5	-35.9
Q1, Q3	-57.1, 27.7	-62.0, 2.8
Min, Max	-100.0, 3100.0	-100.0, 450.0
Difference in Percent Change from Baseline at Week 16		
n [1]	68	73
n [2]	57	68
MMRM: Least Squares Mean [SE] (95% CI)	116.82 [60.51] (-2.87, 236.51)	-19.67 [56.69] (-131.80, 92.46)
MMRM: Least Squares Mean Difference [SE] (95% CI)	136.49 [82.68] (-27.05, 300.02)	
MMRM: P-value	0.10	
Corrected Hedges' g (95% CI)	0.293 (-0.061, 0.647)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.091	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-bfi-gba_adhoc.sas V.03.05 Output file: t-chg-bfii-rt.pdf 25JAN2024:11:18

Table 2.6401.03: Analysis of Brief Interference Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
BFIINTER - BFI Interference Score at Week 20		
n	64	83
Mean (SD)	18.8 (16.08)	15.8 (15.03)
Median	16.5	12.0
Q1, Q3	5.0, 29.5	2.0, 25.0
Min, Max	0.0, 60.0	0.0, 56.0
Return Rate (%)	74%	88%
Number of Subjects in Risk	74	90
Return Rate in Risk (%)	86%	92%
Change in BFI Interference Score at Week 20 from Baseline		
n	59	69
Mean (SD)	-3.2 (12.29)	-6.6 (12.44)
Median	-3.0	-5.0
Q1, Q3	-12.0, 7.0	-12.0, 0.0
Min, Max	-42.0, 30.0	-49.0, 21.0
Difference in Change from Baseline at Week 20		
n [1]	73	76
n [2]	59	69
MMRM: Least Squares Mean [SE] (95% CI)	0.11 [1.55] (-2.96, 3.17)	-4.66 [1.45] (-7.52, -1.80)
MMRM: Least Squares Mean Difference [SE] (95% CI)	4.77 [1.95] (0.91, 8.62)	
MMRM: P-value	0.016	
Corrected Hedges' g (95% CI)	0.396 (0.045, 0.747)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.12	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-bfi-gba_adhoc.sas V.03.05 Output file: t-chg-bfii-rt.pdf 25JAN2024:11:18

Table 2.6401.03: Analysis of Brief Interference Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Percent Change in BFI Interference Score at Week 20 from Baseline		
n	56	67
Mean (SD)	5.9 (135.13)	-27.0 (83.21)
Median	-26.9	-40.0
Q1, Q3	-55.9, 23.0	-71.4, 0.0
Min, Max	-100.0, 800.0	-100.0, 525.0
Difference in Percent Change from Baseline at Week 20		
n [1]	68	73
n [2]	56	67
MMRM: Least Squares Mean [SE] (95% CI)	50.25 [30.77] (-10.61, 111.11)	-21.75 [28.75] (-78.61, 35.12)
MMRM: Least Squares Mean Difference [SE] (95% CI)	72.00 [41.64] (-10.37, 154.37)	
MMRM: P-value	0.086	
Corrected Hedges' g (95% CI)	0.307 (-0.050, 0.664)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.065	
BFIINTER - BFI Interference Score at Week 24		
n	65	82
Mean (SD)	16.2 (13.38)	14.1 (13.90)
Median	13.0	10.5
Q1, Q3	6.0, 24.0	3.0, 21.0
Min, Max	0.0, 57.0	0.0, 60.0
Return Rate (%)	76%	87%
Number of Subjects in Risk	70	87
Return Rate in Risk (%)	93%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-bfi-gba_adhoc.sas V.03.05 Output file: t-chg-bfii-rt.pdf 25JAN2024:11:18

Table 2.6401.03: Analysis of Brief Interference Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Change in BFI Interference Score at Week 24 from Baseline		
n	59	68
Mean (SD)	-4.9 (12.71)	-7.2 (11.72)
Median	-3.0	-5.5
Q1, Q3	-12.0, 2.0	-12.5, 0.0
Min, Max	-42.0, 31.0	-50.0, 28.0
Difference in Change from Baseline at Week 24		
n [1]	73	76
n [2]	59	68
MMRM: Least Squares Mean [SE] (95% CI)	-1.89 [1.44] (-4.73, 0.95)	-5.40 [1.35] (-8.06, -2.73)
MMRM: Least Squares Mean Difference [SE] (95% CI)	3.50 [1.79] (-0.03, 7.04)	
MMRM: P-value	0.052	
Corrected Hedges' g (95% CI)	0.314 (-0.037, 0.665)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.063	
Percent Change in BFI Interference Score at Week 24 from Baseline		
n	55	65
Mean (SD)	48.8 (428.60)	-25.1 (103.44)
Median	-22.5	-37.5
Q1, Q3	-60.0, 20.0	-75.0, -11.1
Min, Max	-100.0, 3100.0	-100.0, 700.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.6401.03: Analysis of Brief Interference Inventory Score and Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Difference in Percent Change from Baseline at Week 24		
n [1]	68	73
n [2]	55	65
MMRM: Least Squares Mean [SE] (95% CI)	45.40 [35.99] (-25.78, 116.59)	-16.84 [33.58] (-83.26, 49.58)
MMRM: Least Squares Mean Difference [SE] (95% CI)	62.24 [48.82] (-34.33, 158.81)	
MMRM: P-value	0.20	
Corrected Hedges' g (95% CI)	0.230 (-0.130, 0.590)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.086	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

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Table 2.6119: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #19 at Week 24
Double-blind Phase
ITT-Anemic Analysis Set

	MMB (N = 86)	RUX (N = 94)	Total (N = 180)
BFI0101 - Fatigue Right Now at Week 24			
Responder, n(%)	21 (24.4%)	25 (26.6%)	46 (25.6%)
Unadjusted Inverse Relative Risk (95% CI)	1.09 (0.66, 1.80)		
p-value [1]	0.74		
Unadjusted Inverse Odds Ratio (95% CI)	1.12 (0.57, 2.20)		
p-value [1]	0.74		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.15, 0.11)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.13 (0.70, 1.85)		
p-value [2]	0.61		
Non-Responder, n(%)	65 (75.6%)	69 (73.4%)	134 (74.4%)
Non-missing	38 (44.2%)	43 (45.7%)	81 (45.0%)
Missing	27 (31.4%)	26 (27.7%)	53 (29.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-item-mpnsaf-gba-improv.sas V.03.05 Output file: t-gba-improv-BFI0101.pdf 29AUG2023: 9:40

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Table 2.6120: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #20 at Week 24

Double-blind Phase

ITT-Anemic Analysis Set

	MMB (N = 86)	RUX (N = 94)	Total (N = 180)
BFI0102 - Usual Fatigue Level Past 24 Hours at Week 24			
Responder, n(%)	19 (22.1%)	27 (28.7%)	46 (25.6%)
Unadjusted Inverse Relative Risk (95% CI)	1.30 (0.78, 2.16)		
p-value [1]	0.31		
Unadjusted Inverse Odds Ratio (95% CI)	1.42 (0.72, 2.80)		
p-value [1]	0.31		
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.19, 0.06)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Non-Responder, n(%)	67 (77.9%)	67 (71.3%)	134 (74.4%)
Non-missing	40 (46.5%)	41 (43.6%)	81 (45.0%)
Missing	27 (31.4%)	26 (27.7%)	53 (29.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

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Table 2.6121: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #21 at Week 24

Double-blind Phase

ITT-Anemic Analysis Set

	MMB (N = 86)	RUX (N = 94)	Total (N = 180)
BFI0103 - Worst Fatigue Level Past 24 Hours at Week 24			
Responder, n(%)	28 (32.6%)	26 (27.7%)	54 (30.0%)
Unadjusted Inverse Relative Risk (95% CI)	0.85 (0.54, 1.33)		
p-value [1]	0.47		
Unadjusted Inverse Odds Ratio (95% CI)	0.79 (0.42, 1.50)		
p-value [1]	0.47		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.09, 0.18)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.90 (0.58, 1.39)		
p-value [2]	0.62		
Non-Responder, n(%)	58 (67.4%)	68 (72.3%)	126 (70.0%)
Non-missing	31 (36.0%)	42 (44.7%)	73 (40.6%)
Missing	27 (31.4%)	26 (27.7%)	53 (29.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

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Table 2.6122: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #22 at Week 24

Double-blind Phase

ITT-Anemic Analysis Set

	MMB (N = 86)	RUX (N = 94)	Total (N = 180)
BFI0104 - Interfered Activity Past 24 Hours at Week 24			
Responder, n(%)	21 (24.4%)	32 (34.0%)	53 (29.4%)
Unadjusted Inverse Relative Risk (95% CI)	1.39 (0.87, 2.22)		
p-value [1]	0.16		
Unadjusted Inverse Odds Ratio (95% CI)	1.60 (0.83, 3.06)		
p-value [1]	0.16		
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.23, 0.04)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.44 (0.92, 2.27)		
p-value [2]	0.11		
Non-Responder, n(%)	65 (75.6%)	62 (66.0%)	127 (70.6%)
Non-missing	38 (44.2%)	36 (38.3%)	74 (41.1%)
Missing	27 (31.4%)	26 (27.7%)	53 (29.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

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Table 2.6123: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #23 at Week 24

Double-blind Phase

ITT-Anemic Analysis Set

	MMB (N = 86)	RUX (N = 94)	Total (N = 180)
BFI0105 - Interfered Mood Past 24 Hours at Week 24			
Responder, n(%)	16 (18.6%)	24 (25.5%)	40 (22.2%)
Unadjusted Inverse Relative Risk (95% CI)	1.37 (0.78, 2.40)		
p-value [1]	0.27		
Unadjusted Inverse Odds Ratio (95% CI)	1.50 (0.73, 3.06)		
p-value [1]	0.27		
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.19, 0.05)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Non-Responder, n(%)	70 (81.4%)	70 (74.5%)	140 (77.8%)
Non-missing	43 (50.0%)	44 (46.8%)	87 (48.3%)
Missing	27 (31.4%)	26 (27.7%)	53 (29.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

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Table 2.6124: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #24 at Week 24
Double-blind Phase
ITT-Anemic Analysis Set

	MMB (N = 86)	RUX (N = 94)	Total (N = 180)
BFI0106 - Interfered Walking Past 24 Hours at Week 24			
Responder, n(%)	21 (24.4%)	28 (29.8%)	49 (27.2%)
Unadjusted Inverse Relative Risk (95% CI)	1.22 (0.75, 1.98)		
p-value [1]	0.42		
Unadjusted Inverse Odds Ratio (95% CI)	1.31 (0.68, 2.54)		
p-value [1]	0.42		
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.18, 0.08)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.23 (0.76, 1.98)		
p-value [2]	0.40		
Non-Responder, n(%)	65 (75.6%)	66 (70.2%)	131 (72.8%)
Non-missing	38 (44.2%)	40 (42.6%)	78 (43.3%)
Missing	27 (31.4%)	26 (27.7%)	53 (29.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-item-mpnsaf-gba-improv.sas V.03.05 Output file: t-gba-improv-BFI0106.pdf 29AUG2023: 9:40

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Table 2.6125: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #25 at Week 24
Double-blind Phase
ITT-Anemic Analysis Set

	MMB (N = 86)	RUX (N = 94)	Total (N = 180)
BFI0107 - Interfered Work Past 24 Hours at Week 24			
Responder, n(%)	21 (24.4%)	33 (35.1%)	54 (30.0%)
Unadjusted Inverse Relative Risk (95% CI)	1.44 (0.91, 2.28)		
p-value [1]	0.12		
Unadjusted Inverse Odds Ratio (95% CI)	1.67 (0.87, 3.20)		
p-value [1]	0.12		
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.24, 0.03)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.48 (0.94, 2.31)		
p-value [2]	0.091		
Non-Responder, n(%)	65 (75.6%)	61 (64.9%)	126 (70.0%)
Non-missing	38 (44.2%)	35 (37.2%)	73 (40.6%)
Missing	27 (31.4%)	26 (27.7%)	53 (29.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-item-mpnsaf-gba-improv.sas V.03.05 Output file: t-gba-improv-BFI0107.pdf 29AUG2023: 9:41

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Study GS-US-352-0101

Table 2.6126: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #26 at Week 24

Double-blind Phase

ITT-Anemic Analysis Set

	MMB (N = 86)	RUX (N = 94)	Total (N = 180)
BFI0108 - Interfered Relations Past 24 Hours at Week 24			
Responder, n(%)	18 (20.9%)	17 (18.1%)	35 (19.4%)
Unadjusted Inverse Relative Risk (95% CI)	0.86 (0.48, 1.57)		
p-value [1]	0.63		
Unadjusted Inverse Odds Ratio (95% CI)	0.83 (0.40, 1.75)		
p-value [1]	0.63		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.09, 0.14)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Non-Responder, n(%)	68 (79.1%)	77 (81.9%)	145 (80.6%)
Non-missing	41 (47.7%)	51 (54.3%)	92 (51.1%)
Missing	27 (31.4%)	26 (27.7%)	53 (29.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

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Table 2.6127: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #27 at Week 24
Double-blind Phase
ITT-Anemic Analysis Set

	MMB (N = 86)	RUX (N = 94)	Total (N = 180)
BFI0109 - Interfered Enjoyment Past 24 Hours at Week 24			
Responder, n(%)	25 (29.1%)	28 (29.8%)	53 (29.4%)
Unadjusted Inverse Relative Risk (95% CI)	1.02 (0.65, 1.61)		
p-value [1]	0.92		
Unadjusted Inverse Odds Ratio (95% CI)	1.04 (0.54, 1.97)		
p-value [1]	0.92		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.14, 0.13)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Non-Responder, n(%)	61 (70.9%)	66 (70.2%)	127 (70.6%)
Non-missing	34 (39.5%)	40 (42.6%)	74 (41.1%)
Missing	27 (31.4%)	26 (27.7%)	53 (29.4%)

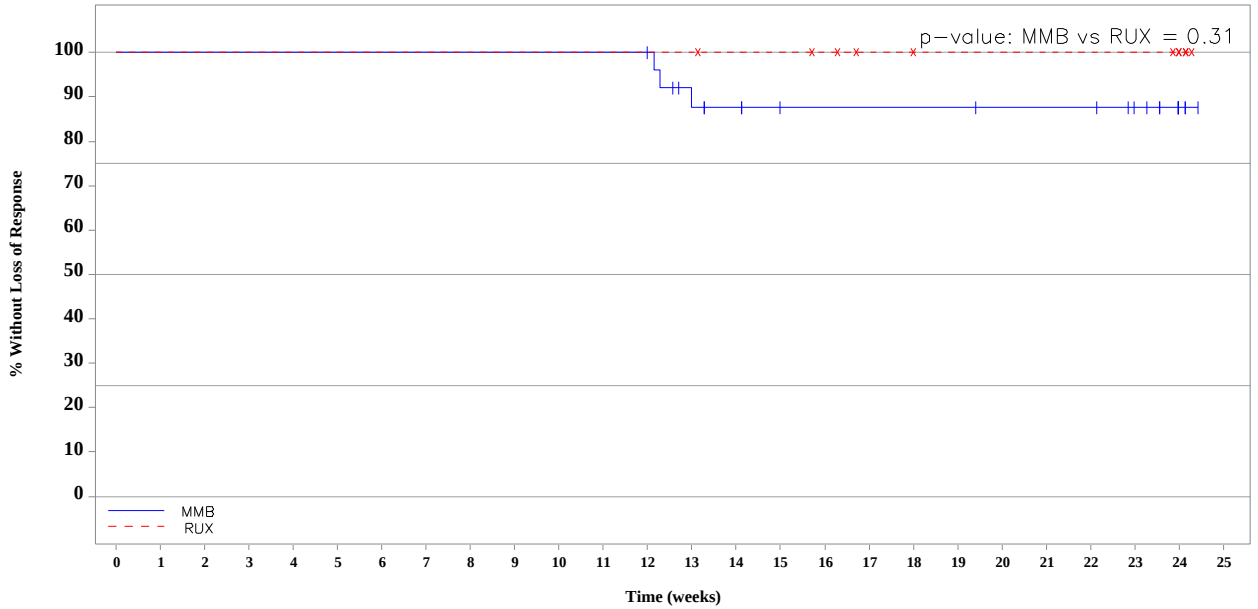
ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-item-mpnsaf-gba-improv.sas V.03.05 Output file: t-gba-improv-BFI0109.pdf 29AUG2023: 9:41

1.6 Transfusionen

1.6.1 TI

Figure 2.2301: Kaplan-Meier Plot of Duration of RBC Transfusion Independent Response
Double-blind Phase
ITT-Anemic Analysis Set who are not Transfusion Independent at baseline but at any Post-baseline



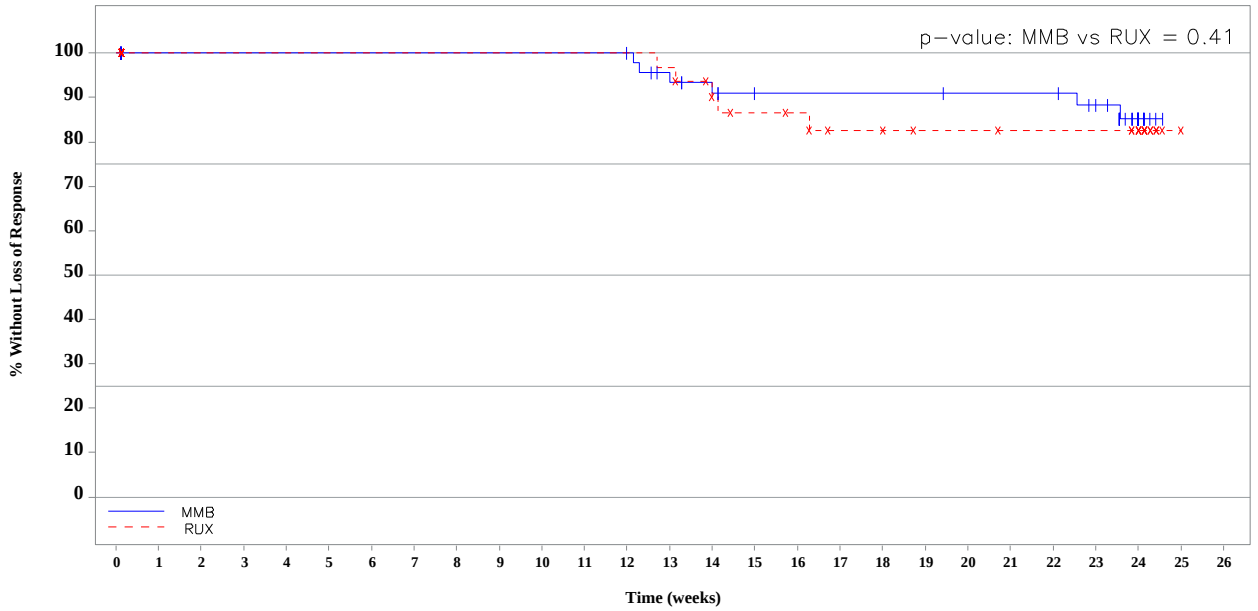
N at Risk (Events)

MMB	26 (0)	26 (0)	26 (0)	26 (0)	26 (0)	26 (0)	26 (0)	26 (0)	26 (0)	26 (0)	26 (0)	26 (0)	26 (0)	21 (3)	18 (3)	16 (3)	15 (3)	15 (3)	15 (3)	15 (3)	14 (3)	14 (3)	14 (3)	12 (3)	8 (3)	0 (3)
RUX	11 (0)	11 (0)	11 (0)	11 (0)	11 (0)	11 (0)	11 (0)	11 (0)	11 (0)	11 (0)	11 (0)	11 (0)	11 (0)	11 (0)	10 (0)	10 (0)	9 (0)	7 (0)	7 (0)	6 (0)	6 (0)	6 (0)	6 (0)	6 (0)	5 (0)	0 (0)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L).

Data Extracted: CRF data: 01JUL2019
Source: g-dur-ti-tib.sas V.03.05 Output file: g-dur-ti-tib.pdf 29AUG2023:15:23

Figure 2.2401: Kaplan-Meier Plot of Duration of RBC Transfusion Independent Response
Double-blind Phase
ITT-Anemic Analysis Set



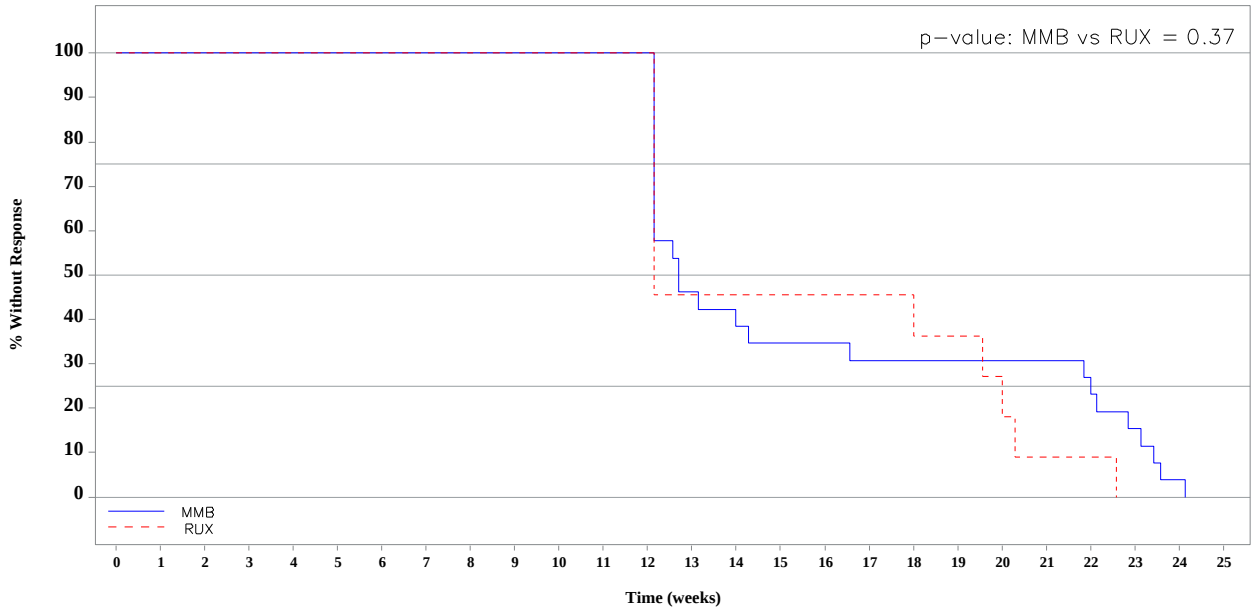
N at Risk (Events)

MMB	86 (0)	47 (0)	47 (0)	47 (0)	47 (0)	47 (0)	47 (0)	47 (0)	47 (0)	47 (0)	47 (0)	47 (0)	47 (0)	42 (3)	39 (4)	36 (4)	35 (4)	35 (4)	35 (4)	34 (4)	34 (4)	34 (4)	31 (5)	19 (6)	0 (6)	0 (6)
RUX	94 (0)	31 (0)	31 (0)	31 (0)	31 (0)	31 (0)	31 (0)	31 (0)	31 (0)	31 (0)	31 (0)	31 (0)	31 (0)	30 (1)	27 (3)	23 (4)	22 (4)	19 (5)	19 (5)	17 (5)	17 (5)	16 (5)	16 (5)	16 (5)	14 (5)	1 (5)	0 (5)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L).

Data Extracted: CRF data: 01JUL2019
Source: g-dur-ti.sas V.03.05 Output file: g-dur-ti.pdf 29AUG2023:15:19

Figure 2.2101: Kaplan-Meier Plot of Time to RBC Transfusion Independent Response
Double-blind Phase
ITT-Anemic Analysis Set who are not Transfusion Independent at baseline but at any Post-baseline



N at Risk (Events)

MMB	26 (0)	26 (0)	26 (0)	26 (0)	26 (0)	26 (0)	26 (0)	26 (0)	26 (0)	26 (0)	26 (0)	26 (0)	26 (0)	12 (14)	11 (16)	9 (17)	9 (17)	8 (18)	8 (18)	8 (18)	8 (18)	8 (18)	7 (20)	4 (22)	1 (25)	0 (26)
RUX	11 (0)	11 (0)	11 (0)	11 (0)	11 (0)	11 (0)	11 (0)	11 (0)	11 (0)	11 (0)	11 (0)	11 (0)	11 (0)	5 (6)	5 (6)	5 (6)	5 (6)	5 (6)	5 (7)	4 (7)	3 (9)	1 (10)	1 (10)	0 (11)	0 (11)	0 (11)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L).

Data Extracted: CRF data: 01JUL2019
Source: g-tte-ti-tib.sas V.03.05 Output file: g-tte-ti-tib.pdf 29AUG2023:15:18

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Table 2.4201: Analysis of response rate of no Transfusion of Any Type for 24 weeks

Double-blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Any Type Transfusion Free Rate			
Responder, n(%)	33 (38.4%)	19 (20.2%)	52 (28.9%)
95% Exact CI	0.2808, 0.4949	0.1263, 0.2975	0.2239, 0.3610
Proportion Difference - Unstratified Exact Method (95% CI)	0.18 (0.04, 0.32)		
p-value	0.009		
Unadjusted Inverse Relative Risk (95% CI)	0.53 (0.33, 0.85)		
p-value [1]	0.009		
Unadjusted Inverse Odds Ratio (95% CI)	0.41 (0.21, 0.79)		
p-value [1]	0.008		
Unadjusted Absolute Risk Difference (95% CI)	0.18 (0.05, 0.31)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.47 (0.30, 0.75)		
p-value [2]	0.001		
Non-responder, n(%)	53 (61.6%)	75 (79.8%)	128 (71.1%)
Any Type Transfusion within 24 weeks	47 (54.7%)	74 (78.7%)	121 (67.2%)
Discontinued prior to week 24	6 (7.0%)	1 (1.1%)	7 (3.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

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Table 2.3702: Analysis of Duration of RBC Transfusion Independent Response by Age
Double-blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Subjects with Event					
Loss of RBC Transfusion Independent Response, n(%)	1 (4.2%)	1 (2.8%)	5 (8.1%)	4 (6.9%)	
Censor					
Subjects Censored, n(%)	23 (95.8%)	35 (97.2%)	57 (91.9%)	54 (93.1%)	
Non-Responder: Censored at Randomization Date	11 (47.8%)	22 (62.9%)	28 (49.1%)	41 (75.9%)	
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	12 (52.2%)	13 (37.1%)	29 (50.9%)	13 (24.1%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Independent Response (Weeks)					
25-percentile (95% CI)	NE (22.57, NE)	NE (12.71, NE)	NE (13.00, NE)	NE (13.14, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (16.29, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 24.29	0.14, 24.43	0.14, 24.57	0.14, 25.00	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-ti-sub.sas V.03.05 Output file: t-dur-ti-age.pdf 24AUG2023:12:43

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Table 2.3704: Analysis of Duration of RBC Transfusion Independent Response by Region
Double-blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Subjects with Event					
Loss of RBC Transfusion Independent Response, n(%)	5 (9.4%)	3 (5.9%)	1 (3.0%)	2 (4.7%)	
Censor					
Subjects Censored, n(%)	48 (90.6%)	48 (94.1%)	32 (97.0%)	41 (95.3%)	
Non-Responder: Censored at Randomization Date	27 (56.3%)	35 (72.9%)	12 (37.5%)	28 (68.3%)	
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	21 (43.8%)	13 (27.1%)	20 (62.5%)	13 (31.7%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Independent Response (Weeks)					
25-percentile (95% CI)	NE (12.29, NE)	NE (14.00, NE)	NE (13.00, NE)	NE (12.71, NE)	
Median (95% CI)	NE (NE, NE)	NE (16.29, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 24.43	0.14, 24.43	0.14, 24.57	0.14, 25.00	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-ti-sub.sas V.03.05 Output file: t-dur-ti-geo.pdf 24AUG2023:12:43

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Table 2.3707: Analysis of Duration of RBC Transfusion Independent Response by Baseline Hemoglobin Level
Double-blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Subjects with Event					
Loss of RBC Transfusion Independent Response, n(%)	2 (7.1%)	0	4 (6.9%)	5 (6.8%)	
Censor					
Subjects Censored, n(%)	26 (92.9%)	21 (100.0%)	54 (93.1%)	68 (93.2%)	
Non-Responder: Censored at Randomization Date	18 (69.2%)	18 (85.7%)	21 (38.9%)	45 (66.2%)	
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	8 (30.8%)	3 (14.3%)	33 (61.1%)	23 (33.8%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Independent Response (Weeks)					
25-percentile (95% CI)	NE (12.29, NE)	NE (NE, NE)	NE (22.57, NE)	NE (13.14, NE)	
Median (95% CI)	NE (12.29, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 24.43	0.14, 24.00	0.14, 24.57	0.14, 25.00	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-ti-sub.sas V.03.05 Output file: t-dur-ti-hgb.pdf 24AUG2023:12:43

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Table 2.3706: Analysis of Duration of RBC Transfusion Independent Response by Baseline IPSS Two-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Subjects with Event					
Loss of RBC Transfusion Independent Response, n(%)	0	0	6 (10.3%)	5 (7.1%)	
Censor					
Subjects Censored, n(%)	28 (100.0%)	24 (100.0%)	52 (89.7%)	65 (92.9%)	
Non-Responder: Censored at Randomization Date	13 (46.4%)	16 (66.7%)	26 (50.0%)	47 (72.3%)	
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	15 (53.6%)	8 (33.3%)	26 (50.0%)	18 (27.7%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Independent Response (Weeks)					
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (13.00, NE)	NE (12.71, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 24.29	0.14, 24.43	0.14, 24.57	0.14, 25.00	
Stratified Log-Rank Test p-value	NE		0.52		
Adjusted Hazard Ratio (95% CI)	NE		0.87 (0.25, 3.01)		
Unstratified Log-Rank Test p-value	NE		0.86		
Unadjusted Hazard Ratio (95% CI)	NE		0.90 (0.27, 2.96)		
P-value for interaction test					> 0.999

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019

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Table 2.3705: Analysis of Duration of RBC Transfusion Independent Response by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Subjects with Event				
Loss of RBC Transfusion Independent Response, n(%)	0	0	0	0
Censor				
Subjects Censored, n(%)	2 (100.0%)	4 (100.0%)	26 (100.0%)	20 (100.0%)
Non-Responder: Censored at Randomization Date	0	2 (50.0%)	13 (50.0%)	14 (70.0%)
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	2 (100.0%)	2 (50.0%)	13 (50.0%)	6 (30.0%)
Kaplan-Meier Estimate of Duration of RBC Transfusion Independent Response (Weeks)				
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Min, Max	23.57, 24.00	0.14, 24.29	0.14, 24.29	0.14, 24.43
Stratified Log-Rank Test p-value	NA		NA	
Adjusted Hazard Ratio (95% CI)	NA		NA	
Unstratified Log-Rank Test p-value	NA		NA	
Unadjusted Hazard Ratio (95% CI)	NA		NA	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019

Table 2.3705: Analysis of Duration of RBC Transfusion Independent Response by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=58)	High Risk RUX (N=70)	p-value
Subjects with Event			
Loss of RBC Transfusion Independent Response, n(%)	6 (10.3%)	5 (7.1%)	
Censor			
Subjects Censored, n(%)	52 (89.7%)	65 (92.9%)	
Non-Responder: Censored at Randomization Date	26 (50.0%)	47 (72.3%)	
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	26 (50.0%)	18 (27.7%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Independent Response (Weeks)			
25-percentile (95% CI)	NE (13.00, NE)	NE (12.71, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 24.57	0.14, 25.00	
Stratified Log-Rank Test p-value	NA		
Adjusted Hazard Ratio (95% CI)	NA		
Unstratified Log-Rank Test p-value	NA		
Unadjusted Hazard Ratio (95% CI)	NA		
P-value for interaction test			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-ti-sub.sas V.03.05 Output file: t-dur-ti-ipss3.pdf 24AUG2023:12:43

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Table 2.3708: Analysis of Duration of RBC Transfusion Independent Response by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=16)	RUX (N=28)	MMB (N=11)	RUX (N=12)
Subjects with Event				
Loss of RBC Transfusion Independent Response, n(%)	1 (6.3%)	2 (7.1%)	0	1 (8.3%)
Censor				
Subjects Censored, n(%)	15 (93.8%)	26 (92.9%)	11 (100.0%)	11 (91.7%)
Non-Responder: Censored at Randomization Date	10 (66.7%)	20 (76.9%)	5 (45.5%)	10 (90.9%)
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	5 (33.3%)	6 (23.1%)	6 (54.5%)	1 (9.1%)
Kaplan-Meier Estimate of Duration of RBC Transfusion Independent Response (Weeks)				
25-percentile (95% CI)	NE (22.57, NE)	NE (13.14, NE)	NE (NE, NE)	14.14 (14.14, NE)
Median (95% CI)	NE (22.57, NE)	NE (13.14, NE)	NE (NE, NE)	NE (14.14, NE)
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (14.14, NE)
Min, Max	0.14, 24.57	0.14, 24.57	0.14, 24.43	0.14, 24.43
Stratified Log-Rank Test p-value	NA		NA	
Adjusted Hazard Ratio (95% CI)	NA		NA	
Unstratified Log-Rank Test p-value	NA		NA	
Unadjusted Hazard Ratio (95% CI)	NA		NA	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-ti-sub.sas V.03.05 Output file: t-dur-ti-mf.pdf 24AUG2023:12:43

Table 2.3708: Analysis of Duration of RBC Transfusion Independent Response by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	Primary Myelofibrosis MMB (N=59)	Primary Myelofibrosis RUX (N=54)	p-value
Subjects with Event			
Loss of RBC Transfusion Independent Response, n(%)	5 (8.5%)	2 (3.7%)	
Censor			
Subjects Censored, n(%)	54 (91.5%)	52 (96.3%)	
Non-Responder: Censored at Randomization Date	24 (44.4%)	33 (63.5%)	
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	30 (55.6%)	19 (36.5%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Independent Response (Weeks)			
25-percentile (95% CI)	NE (13.00, NE)	NE (12.71, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 24.29	0.14, 25.00	
Stratified Log-Rank Test p-value	NA		
Adjusted Hazard Ratio (95% CI)	NA		
Unstratified Log-Rank Test p-value	NA		
Unadjusted Hazard Ratio (95% CI)	NA		
P-value for interaction test			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-ti-sub.sas V.03.05 Output file: t-dur-ti-mf.pdf 24AUG2023:12:43

Table 2.3601: Analysis of Duration of RBC Transfusion Independent Response
Double-Blind Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline but at any Post-baseline

	MMB (N=26)	RUX (N=11)
All Strata Combined		
Subjects with Event		
Loss of Transfusion Independent response, n(%)	3 (11.5%)	0
Subjects Censored, n(%)	23 (88.5%)	11 (100.0%)
Kaplan-Meier Estimate of Duration of Transfusion Independent (Weeks)		
25-percentile (95% CI)	NE (12.1, NE)	NE
Median (95% CI)	NE	NE
75-percentile (95% CI)	NE	NE
Min, Max	12.0, 24.4	13.1, 24.3
Unstratified Log-Rank Test		
p-value	0.233	
Stratified Log-Rank Test		
p-value	0.313	
Unstratified Hazard Ratio (95% CI)	NE	
Stratified Hazard Ratio (95% CI)	NE	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-dur-ti-ntib.sas V.03.05 Output file: t-dur-ti-ntib.pdf 29AUG2023: 8:57

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Table 2.3703: Analysis of Duration of RBC Transfusion Independent Response by Gender
Double-blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Subjects with Event					
Loss of RBC Transfusion Independent Response, n(%)	5 (10.0%)	3 (5.4%)	1 (2.8%)	2 (5.3%)	
Censor					
Subjects Censored, n(%)	45 (90.0%)	53 (94.6%)	35 (97.2%)	36 (94.7%)	
Non-Responder: Censored at Randomization Date	25 (55.6%)	37 (69.8%)	14 (40.0%)	26 (72.2%)	
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	20 (44.4%)	16 (30.2%)	21 (60.0%)	10 (27.8%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Independent Response (Weeks)					
25-percentile (95% CI)	NE (12.14, NE)	NE (12.71, NE)	NE (22.57, NE)	NE (13.14, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (16.29, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 24.57	0.14, 25.00	0.14, 24.14	0.14, 24.57	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-ti-sub.sas V.03.05 Output file: t-dur-ti-sex.pdf 24AUG2023:12:43

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Table 2.3710: Analysis of Duration of RBC Transfusion Independent Response by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Subjects with Event					
Loss of RBC Transfusion Independent Response, n(%)	3 (6.4%)	1 (2.3%)	3 (7.7%)	4 (7.8%)	
Censor					
Subjects Censored, n(%)	44 (93.6%)	42 (97.7%)	36 (92.3%)	47 (92.2%)	
Non-Responder: Censored at Randomization Date	18 (40.9%)	33 (78.6%)	21 (58.3%)	30 (63.8%)	
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	26 (59.1%)	9 (21.4%)	15 (41.7%)	17 (36.2%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Independent Response (Weeks)					
25-percentile (95% CI)	NE (14.00, NE)	NE (13.14, NE)	NE (12.14, NE)	NE (12.71, NE)	
Median (95% CI)	NE (NE, NE)	NE (13.14, NE)	NE (23.57, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 24.57	0.14, 25.00	0.14, 24.43	0.14, 24.43	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019

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Table 2.3709: Analysis of Duration of RBC Transfusion Independent Response by Baseline TSS
Double-blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Subjects with Event					
Loss of RBC Transfusion Independent Response, n(%)	5 (11.4%)	2 (3.6%)	1 (2.4%)	3 (7.9%)	
Censor					
Subjects Censored, n(%)	39 (88.6%)	53 (96.4%)	40 (97.6%)	35 (92.1%)	
Non-Responder: Censored at Randomization Date	18 (46.2%)	35 (66.0%)	21 (52.5%)	27 (77.1%)	
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	21 (53.8%)	18 (34.0%)	19 (47.5%)	8 (22.9%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Independent Response (Weeks)					
25-percentile (95% CI)	NE (12.29, NE)	NE (13.14, NE)	NE (22.57, NE)	16.29 (12.71, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (14.14, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 24.29	0.14, 25.00	0.14, 24.57	0.14, 24.57	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-ti-sub.sas V.03.05 Output file: t-dur-ti-tss.pdf 24AUG2023:12:43

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Table 2.3701: Analysis of Duration of RBC Transfusion Independent Response
Double-blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Subjects with Event		
Loss of RBC Transfusion Independent Response, n(%)	6 (7.0%)	5 (5.3%)
Censor		
Subjects Censored, n(%)	80 (93.0%)	89 (94.7%)
Non-Responder: Censored at Randomization Date	39 (48.8%)	63 (70.8%)
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	41 (51.3%)	26 (29.2%)
Kaplan-Meier Estimate of Duration of RBC Transfusion Independent Response (Weeks)		
25-percentile (95% CI)	NE (22.57, NE)	NE (14.00, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)
Min, Max	0.14, 24.57	0.14, 25.00
Stratified Log-Rank Test p-value	0.41	
Adjusted Hazard Ratio (95% CI)	0.71 (0.21, 2.45)	
Unstratified Log-Rank Test p-value	0.69	
Unadjusted Hazard Ratio (95% CI)	0.78 (0.24, 2.58)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-ti.sas V.03.05 Output file: t-dur-ti.pdf 24AUG2023:12:43

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Table 2.3302: Analysis of New RBC Transfusion Independent Response Rate by Week 24 by Age

Double-Blind Phase

ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	<65 Years		>=65 Years		
	MMB (N=12)	RUX (N=19)	MMB (N=37)	RUX (N=24)	p-value
RBC Transfusion Independent Rate by Week 24					
Responder, n(%)	4 (33.3%)	5 (26.3%)	15 (40.5%)	3 (12.5%)	
95% Exact CI	0.0992, 0.6511	0.0915, 0.5120	0.2475, 0.5790	0.0266, 0.3236	
Proportion Difference - Stratified CMH Method (95% CI)	0.10 (-0.31, 0.50)		0.27 (0.04, 0.51)		
p-value	0.65		0.024		
Proportion Difference - Unstratified CMH Method (95% CI)	0.07 (-0.28, 0.42)		0.28 (0.07, 0.49)		
p-value	0.69		0.010		
Proportion Difference - Unstratified Exact Method (95% CI)	0.07 (-0.29, 0.42)		0.28 (0.02, 0.51)		
p-value	0.70		0.023		
Unadjusted Inverse Relative Risk (95% CI)	0.79 (0.26, 2.37)		0.31 (0.10, 0.95)		
p-value [1]	0.67		0.041		
Unadjusted interaction test for Treatment*Age Group [3]					0.23
Unadjusted Inverse Odds Ratio (95% CI)	0.71 (0.15, 3.45)		0.21 (0.05, 0.83)		
p-value [1]	0.68		0.026		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.26, 0.40)		0.28 (0.07, 0.49)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.72 (0.23, 2.22)		0.32 (0.10, 0.98)		
p-value [2]	0.57		0.045		
Adjusted interaction test for Treatment*Age Group [3]					0.28
Non-Responder, n(%)	8 (66.7%)	14 (73.7%)	22 (59.5%)	21 (87.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

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Table 2.3308: Analysis of New RBC Transfusion Independent Response Rate by Week 24 by Baseline MF Disease Status

Double-Blind Phase

ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=33)	RUX (N=27)	MMB (N=7)	RUX (N=10)
RBC Transfusion Independent Rate by Week 24				
Responder, n(%)	15 (45.5%)	7 (25.9%)	0	1 (10.0%)
95% Exact CI	0.2811, 0.6365	0.1111, 0.4628	0.0000, 0.4096	0.0025, 0.4450
Proportion Difference - Stratified CMH Method (95% CI)	0.18 (-0.07, 0.43)		-0.09 (-0.48, 0.30)	
p-value	0.15		0.65	
Proportion Difference - Unstratified CMH Method (95% CI)	0.20 (-0.05, 0.44)		-0.10 (-0.40, 0.20)	
p-value	0.11		0.51	
Proportion Difference - Unstratified Exact Method (95% CI)	0.20 (-0.06, 0.43)		-0.10 (-0.54, 0.37)	
p-value	0.18		1.00	
Unadjusted Inverse Relative Risk (95% CI)	0.57 (0.27, 1.19)		2.18 (0.10, 46.92)	
p-value [1]	0.14		0.62	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.42 (0.14, 1.26)		2.37 (0.08, 66.89)	
p-value [1]	0.12		0.61	
Unadjusted Absolute Risk Difference (95% CI)	0.20 (-0.04, 0.43)		-0.07 (-0.34, 0.19)	
Adjusted Inverse Relative Risk (95% CI) [2]	0.59 (0.28, 1.23)		NE	
p-value [2]	0.16		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	18 (54.5%)	20 (74.1%)	7 (100.0%)	9 (90.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.3308: Analysis of New RBC Transfusion Independent Response Rate by Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	Post-PV Myelofibrosis		
	MMB (N=9)	RUX (N=6)	p-value
RBC Transfusion Independent Rate by Week 24			
Responder, n(%)	4 (44.4%)	0	
95% Exact CI	0.1370, 0.7880	0.0000, 0.4593	
Proportion Difference - Stratified CMH Method (95% CI)	0.43 (-0.20, 1.06)		
p-value	0.18		
Proportion Difference - Unstratified CMH Method (95% CI)	0.44 (0.03, 0.86)		
p-value	0.035		
Proportion Difference - Unstratified Exact Method (95% CI)	0.44 (-0.10, 0.82)		
p-value	0.10		
Unadjusted Inverse Relative Risk (95% CI)	0.16 (0.01, 2.50)		
p-value [1]	0.19		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE
Unadjusted Inverse Odds Ratio (95% CI)	0.09 (0.00, 2.16)		
p-value [1]	0.14		
Unadjusted Absolute Risk Difference (95% CI)	0.38 (0.02, 0.74)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE
Non-Responder, n(%)	5 (55.6%)	6 (100.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019

GSK Oncology

Study GS-US-352-0101

Table 2.3307: Analysis of New RBC Transfusion Independent Response Rate by Week 24 by Baseline Hemoglobin Level

Double-Blind Phase

ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=21)	RUX (N=22)	p-value
RBC Transfusion Independent Rate by Week 24					
Responder, n(%)	10 (35.7%)	3 (14.3%)	9 (42.9%)	5 (22.7%)	
95% Exact CI	0.1864, 0.5593	0.0305, 0.3634	0.2182, 0.6598	0.0782, 0.4537	
Proportion Difference - Stratified CMH Method (95% CI)	0.22 (-0.04, 0.47)		0.20 (-0.10, 0.51)		
p-value	0.099		0.19		
Proportion Difference - Unstratified CMH Method (95% CI)	0.21 (-0.03, 0.46)		0.20 (-0.08, 0.48)		
p-value	0.083		0.16		
Proportion Difference - Unstratified Exact Method (95% CI)	0.21 (-0.07, 0.48)		0.20 (-0.11, 0.47)		
p-value	0.11		0.20		
Unadjusted Inverse Relative Risk (95% CI)	0.40 (0.13, 1.28)		0.53 (0.21, 1.32)		
p-value [1]	0.12		0.17		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.70
Unadjusted Inverse Odds Ratio (95% CI)	0.30 (0.07, 1.27)		0.39 (0.10, 1.47)		
p-value [1]	0.10		0.16		
Unadjusted Absolute Risk Difference (95% CI)	0.21 (-0.02, 0.45)		0.20 (-0.07, 0.48)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.40 (0.12, 1.27)		0.52 (0.21, 1.32)		
p-value [2]	0.12		0.17		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.71
Non-Responder, n(%)	18 (64.3%)	18 (85.7%)	12 (57.1%)	17 (77.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

GSK Oncology

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Table 2.3306: Analysis of New RBC Transfusion Independent Response Rate by Week 24 by Baseline IPSS Two-Level Risk

Double-Blind Phase

ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	Intermediate Risk		High Risk		
	MMB (N=14)	RUX (N=8)	MMB (N=35)	RUX (N=35)	p-value
RBC Transfusion Independent Rate by Week 24					
Responder, n(%)	4 (28.6%)	0	15 (42.9%)	8 (22.9%)	
95% Exact CI	0.0839, 0.5810	0.0000, 0.3694	0.2632, 0.6065	0.1042, 0.4014	
Proportion Difference - Stratified CMH Method (95% CI)	0.30 (-0.17, 0.77)		0.19 (-0.03, 0.42)		
p-value	0.21		0.097		
Proportion Difference - Unstratified CMH Method (95% CI)	0.29 (-0.02, 0.59)		0.20 (-0.02, 0.42)		
p-value	0.063		0.074		
Proportion Difference - Unstratified Exact Method (95% CI)	0.29 (-0.15, 0.66)		0.20 (-0.05, 0.43)		
p-value	0.25		0.13		
Unadjusted Inverse Relative Risk (95% CI)	0.19 (0.01, 3.05)		0.53 (0.26, 1.09)		
p-value [1]	0.24		0.087		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NE
Unadjusted Inverse Odds Ratio (95% CI)	0.14 (0.01, 2.92)		0.40 (0.14, 1.11)		
p-value [1]	0.20		0.079		
Unadjusted Absolute Risk Difference (95% CI)	0.24 (-0.03, 0.52)		0.20 (-0.02, 0.42)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.55 (0.27, 1.11)		
p-value [2]	NE		0.096		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NE
Non-Responder, n(%)	10 (71.4%)	8 (100.0%)	20 (57.1%)	27 (77.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019

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Table 2.3305: Analysis of New RBC Transfusion Independent Response Rate by Week 24 by Baseline IPSS Three-Level Risk

Double-Blind Phase

ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=0)	RUX (N=1)	MMB (N=14)	RUX (N=7)
RBC Transfusion Independent Rate by Week 24				
Responder, n(%)	0	0	4 (28.6%)	0
95% Exact CI	NA, NA	0.0000, 0.9750	0.0839, 0.5810	0.0000, 0.4096
Proportion Difference - Stratified CMH Method (95% CI)	NA		0.29 (-0.15, 0.72)	
p-value	NA		0.20	
Proportion Difference - Unstratified CMH Method (95% CI)	NA		0.29 (-0.03, 0.60)	
p-value	NA		0.076	
Proportion Difference - Unstratified Exact Method (95% CI)	NA		0.29 (-0.20, 0.71)	
p-value	NA		0.25	
Unadjusted Inverse Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	0	1 (100.0%)	10 (71.4%)	7 (100.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

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Table 2.3305: Analysis of New RBC Transfusion Independent Response Rate by Week 24 by Baseline IPSS Three-Level Risk

Double-Blind Phase

ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	High Risk		
	MMB (N=35)	RUX (N=35)	p-value
RBC Transfusion Independent Rate by Week 24			
Responder, n(%)	15 (42.9%)	8 (22.9%)	
95% Exact CI	0.2632, 0.6065	0.1042, 0.4014	
Proportion Difference - Stratified CMH Method (95% CI)	0.19 (-0.03, 0.42)		
p-value	0.097		
Proportion Difference - Unstratified CMH Method (95% CI)	0.20 (-0.02, 0.42)		
p-value	0.074		
Proportion Difference - Unstratified Exact Method (95% CI)	0.20 (-0.05, 0.43)		
p-value	0.13		
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	20 (57.1%)	27 (77.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

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Table 2.3304: Analysis of New RBC Transfusion Independent Response Rate by Week 24 by Region

Double-Blind Phase

ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	Western Countries		Eastern Countries		
	MMB (N=34)	RUX (N=23)	MMB (N=15)	RUX (N=20)	p-value
RBC Transfusion Independent Rate by Week 24					
Responder, n(%)	13 (38.2%)	3 (13.0%)	6 (40.0%)	5 (25.0%)	
95% Exact CI	0.2217, 0.5644	0.0278, 0.3359	0.1634, 0.6771	0.0866, 0.4910	
Proportion Difference - Stratified CMH Method (95% CI)	0.26 (0.02, 0.50)		0.16 (-0.19, 0.51)		
p-value	0.035		0.37		
Proportion Difference - Unstratified CMH Method (95% CI)	0.25 (0.03, 0.47)		0.15 (-0.17, 0.47)		
p-value	0.026		0.36		
Proportion Difference - Unstratified Exact Method (95% CI)	0.25 (-0.02, 0.49)		0.15 (-0.19, 0.47)		
p-value	0.070		0.47		
Unadjusted Inverse Relative Risk (95% CI)	0.34 (0.11, 1.06)		0.63 (0.23, 1.67)		
p-value [1]	0.064		0.35		
Unadjusted interaction test for Treatment*Region [3]					0.42
Unadjusted Inverse Odds Ratio (95% CI)	0.24 (0.06, 0.98)		0.50 (0.12, 2.12)		
p-value [1]	0.047		0.35		
Unadjusted Absolute Risk Difference (95% CI)	0.25 (0.04, 0.47)		0.15 (-0.16, 0.46)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.33 (0.11, 1.04)		0.61 (0.23, 1.58)		
p-value [2]	0.059		0.31		
Adjusted interaction test for Treatment*Region [3]					0.40
Non-Responder, n(%)	21 (61.8%)	20 (87.0%)	9 (60.0%)	15 (75.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

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Table 2.3303: Analysis of New RBC Transfusion Independent Response Rate by Week 24 by Gender

Double-Blind Phase

ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	Male		Female		
	MMB (N=35)	RUX (N=28)	MMB (N=14)	RUX (N=15)	p-value
RBC Transfusion Independent Rate by Week 24					
Responder, n(%)	13 (37.1%)	5 (17.9%)	6 (42.9%)	3 (20.0%)	
95% Exact CI	0.2147, 0.5508	0.0606, 0.3689	0.1766, 0.7114	0.0433, 0.4809	
Proportion Difference - Stratified CMH Method (95% CI)	0.19 (-0.05, 0.42)		0.17 (-0.25, 0.58)		
p-value	0.12		0.43		
Proportion Difference - Unstratified CMH Method (95% CI)	0.19 (-0.03, 0.41)		0.23 (-0.12, 0.57)		
p-value	0.086		0.19		
Proportion Difference - Unstratified Exact Method (95% CI)	0.19 (-0.06, 0.43)		0.23 (-0.16, 0.55)		
p-value	0.16		0.25		
Unadjusted Inverse Relative Risk (95% CI)	0.48 (0.19, 1.19)		0.47 (0.14, 1.52)		
p-value [1]	0.11		0.21		
Unadjusted interaction test for Treatment*Gender [3]					0.97
Unadjusted Inverse Odds Ratio (95% CI)	0.37 (0.11, 1.20)		0.33 (0.06, 1.73)		
p-value [1]	0.098		0.19		
Unadjusted Absolute Risk Difference (95% CI)	0.19 (-0.02, 0.41)		0.23 (-0.10, 0.56)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.49 (0.20, 1.23)		0.58 (0.17, 1.99)		
p-value [2]	0.13		0.38		
Adjusted interaction test for Treatment*Gender [3]					0.98
Non-Responder, n(%)	22 (62.9%)	23 (82.1%)	8 (57.1%)	12 (80.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

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Table 2.3310: Analysis of New RBC Transfusion Independent Response Rate by Week 24 by Baseline Spleen Volume

Double-Blind Phase

ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	<Median (1837.09 cm^3)		>=Median (1837.09 cm^3)		
	MMB (N=24)	RUX (N=17)	MMB (N=25)	RUX (N=26)	p-value
RBC Transfusion Independent Rate by Week 24					
Responder, n(%)	11 (45.8%)	2 (11.8%)	8 (32.0%)	6 (23.1%)	
95% Exact CI	0.2555, 0.6718	0.0146, 0.3644	0.1495, 0.5350	0.0897, 0.4365	
Proportion Difference - Stratified CMH Method (95% CI)	0.34 (0.02, 0.67)		0.12 (-0.14, 0.38)		
p-value	0.039		0.35		
Proportion Difference - Unstratified CMH Method (95% CI)	0.34 (0.08, 0.61)		0.09 (-0.16, 0.34)		
p-value	0.012		0.49		
Proportion Difference - Unstratified Exact Method (95% CI)	0.34 (0.03, 0.61)		0.09 (-0.19, 0.34)		
p-value	0.039		0.54		
Unadjusted Inverse Relative Risk (95% CI)	0.26 (0.07, 1.01)		0.72 (0.29, 1.78)		
p-value [1]	0.052		0.48		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.18
Unadjusted Inverse Odds Ratio (95% CI)	0.16 (0.03, 0.85)		0.64 (0.18, 2.20)		
p-value [1]	0.031		0.48		
Unadjusted Absolute Risk Difference (95% CI)	0.34 (0.09, 0.59)		0.09 (-0.16, 0.33)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.26 (0.06, 1.03)		0.63 (0.25, 1.57)		
p-value [2]	0.055		0.32		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.24
Non-Responder, n(%)	13 (54.2%)	15 (88.2%)	17 (68.0%)	20 (76.9%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

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Table 2.3309: Analysis of New RBC Transfusion Independent Response Rate by Week 24 by Baseline TSS

Double-Blind Phase

ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	<18		>=18		
	MMB (N=28)	RUX (N=26)	MMB (N=20)	RUX (N=16)	p-value
RBC Transfusion Independent Rate by Week 24					
Responder, n(%)	12 (42.9%)	7 (26.9%)	6 (30.0%)	1 (6.3%)	
95% Exact CI	0.2446, 0.6282	0.1157, 0.4779	0.1189, 0.5428	0.0016, 0.3023	
Proportion Difference - Stratified CMH Method (95% CI)	0.16 (-0.11, 0.43)		0.24 (-0.04, 0.53)		
p-value	0.24		0.098		
Proportion Difference - Unstratified CMH Method (95% CI)	0.16 (-0.10, 0.42)		0.24 (-0.02, 0.49)		
p-value	0.22		0.065		
Proportion Difference - Unstratified Exact Method (95% CI)	0.16 (-0.10, 0.42)		0.24 (-0.10, 0.54)		
p-value	0.26		0.10		
Unadjusted Inverse Relative Risk (95% CI)	0.63 (0.29, 1.35)		0.21 (0.03, 1.56)		
p-value [1]	0.23		0.13		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.23
Unadjusted Inverse Odds Ratio (95% CI)	0.49 (0.16, 1.54)		0.16 (0.02, 1.46)		
p-value [1]	0.22		0.10		
Unadjusted Absolute Risk Difference (95% CI)	0.16 (-0.09, 0.41)		0.24 (0.00, 0.47)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.63 (0.29, 1.34)		0.20 (0.03, 1.55)		
p-value [2]	0.23		0.12		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.23
Non-Responder, n(%)	16 (57.1%)	19 (73.1%)	14 (70.0%)	15 (93.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

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Table 2.3301: Analysis of Rate of New RBC Transfusion Independent Response Rate by Week 24

Double-Blind Phase

ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	MMB (N=49)	RUX (N=43)	Total (N=92)
RBC Transfusion Independent Rate by Week 24			
Responder, n(%)	19 (38.8%)	8 (18.6%)	27 (29.3%)
95% Exact CI	0.2520, 0.5376	0.0839, 0.3340	0.2031, 0.3976
Proportion Difference - Stratified CMH Method (95% CI)	0.20 (0.02, 0.39)		
p-value	0.034		
Proportion Difference - Unstratified CMH Method (95% CI)	0.20 (0.02, 0.38)		
p-value	0.030		
Proportion Difference - Unstratified Exact Method (95% CI)	0.20 (0.00, 0.39)		
p-value	0.041		
Unadjusted Inverse Relative Risk (95% CI)	0.48 (0.23, 0.98)		
p-value [1]	0.045		
Unadjusted Inverse Odds Ratio (95% CI)	0.36 (0.14, 0.94)		
p-value [1]	0.037		
Unadjusted Absolute Risk Difference (95% CI)	0.20 (0.02, 0.38)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.48 (0.23, 0.98)		
p-value [2]	0.043		
Non-Responder, n(%)	30 (61.2%)	35 (81.4%)	65 (70.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel.

RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

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Table 2.2802: Analysis of RBC Transfusion Independence Response Rate at Week 24 and Week 12

Double-Blind Phase

ITT-Anemic Analysis Set Who are Not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
All Strata Combined			
RBC Transfusion Independent Rate at Week 24			
Responder, n(%)	22 (36.1%)	11 (20.8%)	33 (28.9%)
95% Exact CI	0.2416, 0.4937	0.1084, 0.3411	0.2084, 0.3819
Proportion Difference - Stratified CMH Method (95% CI)	0.15 (-0.02, 0.32)		
p-value	0.075		
Proportion Difference - Unstratified CMH Method (95% CI)	0.15 (-0.01, 0.32)		
p-value	0.069		
Proportion Difference - Unstratified Exact Method (95% CI)	0.15 (-0.03, 0.33)		
p-value	0.098		
Unadjusted Inverse Relative Risk (95% CI)	0.58 (0.31, 1.07)		
p-value [1]	0.082		
Unadjusted Inverse Odds Ratio (95% CI)	0.46 (0.20, 1.08)		
p-value [1]	0.075		
Unadjusted Absolute Risk Difference (95% CI)	0.15 (-0.01, 0.32)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.57 (0.31, 1.05)		
p-value [2]	0.073		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel.

RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Table 2.2802: Analysis of RBC Transfusion Independence Response Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are Not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
Non-Responder, n(%)	39 (63.9%)	42 (79.2%)	81 (71.1%)
Transfusion (except bleeding) in the last 12 weeks	24 (39.3%)	32 (60.4%)	56 (49.1%)
Any Hgb assessment < 8g/dL in the last 12 weeks	20 (32.8%)	27 (50.9%)	47 (41.2%)
Last Participation date < Day 162 in DB phase	12 (19.7%)	7 (13.2%)	19 (16.7%)
Other	11 (18.0%)	17 (32.1%)	28 (24.6%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

Table 2.2802: Analysis of RBC Transfusion Independence Response Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are Not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
RBC Transfusion Independent Rate at Week 12			
Responder, n(%)	14 (23.0%)	6 (11.3%)	20 (17.5%)
95% Exact CI	0.1315, 0.3550	0.0427, 0.2303	0.1106, 0.2579
Proportion Difference - Stratified CMH Method (95% CI)	0.12 (-0.03, 0.26)		
p-value	0.13		
Proportion Difference - Unstratified CMH Method (95% CI)	0.12 (-0.02, 0.26)		
p-value	0.10		
Proportion Difference - Unstratified Exact Method (95% CI)	0.12 (-0.07, 0.30)		
p-value	0.14		
Unadjusted Inverse Relative Risk (95% CI)	0.49 (0.20, 1.19)		
p-value [1]	0.12		
Unadjusted Inverse Odds Ratio (95% CI)	0.43 (0.15, 1.21)		
p-value [1]	0.11		
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.02, 0.25)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.50 (0.21, 1.18)		
p-value [2]	0.11		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

Table 2.2802: Analysis of RBC Transfusion Independence Response Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are Not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
Non-Responder, n(%)	47 (77.0%)	47 (88.7%)	94 (82.5%)
Transfusion (except bleeding) in the last 12 weeks	38 (62.3%)	43 (81.1%)	81 (71.1%)
Any Hgb assessment < 8g/dL in the last 12 weeks	23 (37.7%)	40 (75.5%)	63 (55.3%)
Last Participation date < Day 78 in DB phase	7 (11.5%)	0	7 (6.1%)
Other	12 (19.7%)	20 (37.7%)	32 (28.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

Table 2.2802: Analysis of RBC Transfusion Independence Response Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are Not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
Stratum 1			
Transfusion Dependence Yes and Platelet Count < 100X10E9/L	**10**	**9**	**19**
RBC Transfusion Independent Rate at Week 24			
Responder, n(%)	**5 (50.0%)**	**2 (22.2%)**	**7 (36.8%)**
95% Exact CI	**0.1871, 0.8129**	**0.0281, 0.6001**	**0.1629, 0.6164**
Proportion Difference (95% CI)	**0.28 (-0.17, 0.72)**		
Proportion Difference using Exact Method (95% CI)	**0.28 (-0.18, 0.67)**		
Non-Responder, n(%)	**5 (50.0%)**	**7 (77.8%)**	**12 (63.2%)**
Transfusion (except bleeding) in the last 12 weeks	**4 (40.0%)**	**4 (44.4%)**	**8 (42.1%)**
Any Hgb assessment < 8g/dL in the last 12 weeks	**3 (30.0%)**	**4 (44.4%)**	**7 (36.8%)**
Last Participation date < Day 162 in DB phase	**1 (10.0%)**	**3 (33.3%)**	**4 (21.1%)**
Other	**1 (10.0%)**	**3 (33.3%)**	**4 (21.1%)**

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Table 2.2802: Analysis of RBC Transfusion Independence Response Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are Not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
RBC Transfusion Independent Rate at Week 12			
Responder, n(%)	2 (20.0%)	1 (11.1%)	3 (15.8%)
95% Exact CI	0.0252, 0.5561	0.0028, 0.4825	0.0338, 0.3958
Proportion Difference (95% CI)	0.09 (-0.28, 0.46)		
Proportion Difference using Exact Method (95% CI)	0.09 (-0.33, 0.51)		
Non-Responder, n(%)	8 (80.0%)	8 (88.9%)	16 (84.2%)
Transfusion (except bleeding) in the last 12 weeks	7 (70.0%)	7 (77.8%)	14 (73.7%)
Any Hgb assessment < 8g/dL in the last 12 weeks	4 (40.0%)	6 (66.7%)	10 (52.6%)
Last Participation date < Day 78 in DB phase	1 (10.0%)	0	1 (5.3%)
Other	1 (10.0%)	4 (44.4%)	5 (26.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

Table 2.2802: Analysis of RBC Transfusion Independence Response Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are Not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
Stratum 2			
Transfusion Dependence Yes and Platelet Count >= 100X10E9/L and <= 200X10E9/L	**20**	**18**	**38**
RBC Transfusion Independent Rate at Week 24			
Responder, n(%)	**7 (35.0%)**	**4 (22.2%)**	**11 (28.9%)**
95% Exact CI	**0.1539, 0.5922**	**0.0641, 0.4764**	**0.1542, 0.4590**
Proportion Difference (95% CI)	**0.13 (-0.17, 0.42)**		
Proportion Difference using Exact Method (95% CI)	**0.13 (-0.19, 0.43)**		
Non-Responder, n(%)	**13 (65.0%)**	**14 (77.8%)**	**27 (71.1%)**
Transfusion (except bleeding) in the last 12 weeks	**7 (35.0%)**	**7 (38.9%)**	**14 (36.8%)**
Any Hgb assessment < 8g/dL in the last 12 weeks	**6 (30.0%)**	**7 (38.9%)**	**13 (34.2%)**
Last Participation date < Day 162 in DB phase	**5 (25.0%)**	**4 (22.2%)**	**9 (23.7%)**
Other	**4 (20.0%)**	**4 (22.2%)**	**8 (21.1%)**

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Table 2.2802: Analysis of RBC Transfusion Independence Response Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are Not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
RBC Transfusion Independent Rate at Week 12			
Responder, n(%)	4 (20.0%)	2 (11.1%)	6 (15.8%)
95% Exact CI	0.0573, 0.4366	0.0138, 0.3471	0.0602, 0.3125
Proportion Difference (95% CI)	0.09 (-0.16, 0.33)		
Proportion Difference using Exact Method (95% CI)	0.09 (-0.24, 0.39)		
Non-Responder, n(%)	16 (80.0%)	16 (88.9%)	32 (84.2%)
Transfusion (except bleeding) in the last 12 weeks	12 (60.0%)	14 (77.8%)	26 (68.4%)
Any Hgb assessment < 8g/dL in the last 12 weeks	9 (45.0%)	14 (77.8%)	23 (60.5%)
Last Participation date < Day 78 in DB phase	3 (15.0%)	0	3 (7.9%)
Other	6 (30.0%)	9 (50.0%)	15 (39.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

Table 2.2802: Analysis of RBC Transfusion Independence Response Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are Not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
Stratum 3			
Transfusion Dependence Yes and Platelet Count > 200X10E9/L	19	16	35
RBC Transfusion Independent Rate at Week 24			
Responder, n(%)	4 (21.1%)	2 (12.5%)	6 (17.1%)
95% Exact CI	0.0605, 0.4557	0.0155, 0.3835	0.0656, 0.3365
Proportion Difference (95% CI)	0.09 (-0.18, 0.35)		
Proportion Difference using Exact Method (95% CI)	0.09 (-0.25, 0.40)		
Non-Responder, n(%)	15 (78.9%)	14 (87.5%)	29 (82.9%)
Transfusion (except bleeding) in the last 12 weeks	10 (52.6%)	14 (87.5%)	24 (68.6%)
Any Hgb assessment < 8g/dL in the last 12 weeks	10 (52.6%)	12 (75.0%)	22 (62.9%)
Last Participation date < Day 162 in DB phase	3 (15.8%)	0	3 (8.6%)
Other	6 (31.6%)	7 (43.8%)	13 (37.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-rbcti24-gba.sas V.03.05 Output file: t-rbcti24-nti-gba.pdf 29AUG2023: 9:37

Table 2.2802: Analysis of RBC Transfusion Independence Response Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are Not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
RBC Transfusion Independent Rate at Week 12			
Responder, n(%)	3 (15.8%)	1 (6.3%)	4 (11.4%)
95% Exact CI	0.0338, 0.3958	0.0016, 0.3023	0.0320, 0.2674
Proportion Difference (95% CI)	0.10 (-0.13, 0.32)		
Proportion Difference using Exact Method (95% CI)	0.10 (-0.24, 0.41)		
Non-Responder, n(%)	16 (84.2%)	15 (93.8%)	31 (88.6%)
Transfusion (except bleeding) in the last 12 weeks	12 (63.2%)	14 (87.5%)	26 (74.3%)
Any Hgb assessment < 8g/dL in the last 12 weeks	8 (42.1%)	14 (87.5%)	22 (62.9%)
Last Participation date < Day 78 in DB phase	3 (15.8%)	0	3 (8.6%)
Other	5 (26.3%)	7 (43.8%)	12 (34.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

Table 2.2802: Analysis of RBC Transfusion Independence Response Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are Not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
Stratum 4			
Transfusion Dependence No and Platelet Count < 100X10E9/L	2	1	3
RBC Transfusion Independent Rate at Week 24			
Responder, n(%)	1 (50.0%)	0	1 (33.3%)
95% Exact CI	0.0126, 0.9874	0.0000, 0.9750	0.0084, 0.9057
Proportion Difference (95% CI)	0.50 (NA, NA)		
Proportion Difference using Exact Method (95% CI)	0.50 (-0.77, 0.99)		
Non-Responder, n(%)	1 (50.0%)	1 (100.0%)	2 (66.7%)
Transfusion (except bleeding) in the last 12 weeks	1 (50.0%)	1 (100.0%)	2 (66.7%)
Any Hgb assessment < 8g/dL in the last 12 weeks	0	1 (100.0%)	1 (33.3%)
Last Participation date < Day 162 in DB phase	0	0	0
Other	0	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

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Table 2.2802: Analysis of RBC Transfusion Independence Response Rate at Week 24 and Week 12

Double-Blind Phase

ITT-Anemic Analysis Set Who are Not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
RBC Transfusion Independent Rate at Week 12			
Responder, n(%)	1 (50.0%)	0	1 (33.3%)
95% Exact CI	0.0126, 0.9874	0.0000, 0.9750	0.0084, 0.9057
Proportion Difference (95% CI)	0.50 (NA, NA)		
Proportion Difference using Exact Method (95% CI)	0.50 (-0.77, 0.99)		
Non-Responder, n(%)	1 (50.0%)	1 (100.0%)	2 (66.7%)
Transfusion (except bleeding) in the last 12 weeks	1 (50.0%)	1 (100.0%)	2 (66.7%)
Any Hgb assessment < 8g/dL in the last 12 weeks	1 (50.0%)	0	1 (33.3%)
Last Participation date < Day 78 in DB phase	0	0	0
Other	0	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel.

RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

Table 2.2802: Analysis of RBC Transfusion Independence Response Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are Not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
Stratum 5			
Transfusion Dependence No and Platelet Count >= 100X10E9/L and <= 200X10E9/L	2	2	4
RBC Transfusion Independent Rate at Week 24			
Responder, n(%)	1 (50.0%)	0	1 (25.0%)
95% Exact CI	0.0126, 0.9874	0.0000, 0.8419	0.0063, 0.8059
Proportion Difference (95% CI)	0.50 (-0.72, 1.72)		
Proportion Difference using Exact Method (95% CI)	0.50 (-0.61, 0.99)		
Non-Responder, n(%)	1 (50.0%)	2 (100.0%)	3 (75.0%)
Transfusion (except bleeding) in the last 12 weeks	1 (50.0%)	2 (100.0%)	3 (75.0%)
Any Hgb assessment < 8g/dL in the last 12 weeks	1 (50.0%)	1 (50.0%)	2 (50.0%)
Last Participation date < Day 162 in DB phase	0	0	0
Other	0	1 (50.0%)	1 (25.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Table 2.2802: Analysis of RBC Transfusion Independence Response Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are Not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
RBC Transfusion Independent Rate at Week 12			
Responder, n(%)	1 (50.0%)	0	1 (25.0%)
95% Exact CI	0.0126, 0.9874	0.0000, 0.8419	0.0063, 0.8059
Proportion Difference (95% CI)	0.50 (-0.72, 1.72)		
Proportion Difference using Exact Method (95% CI)	0.50 (-0.61, 0.99)		
Non-Responder, n(%)	1 (50.0%)	2 (100.0%)	3 (75.0%)
Transfusion (except bleeding) in the last 12 weeks	1 (50.0%)	2 (100.0%)	3 (75.0%)
Any Hgb assessment < 8g/dL in the last 12 weeks	0	2 (100.0%)	2 (50.0%)
Last Participation date < Day 78 in DB phase	0	0	0
Other	0	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

Table 2.2802: Analysis of RBC Transfusion Independence Response Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are Not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
Stratum 6			
Transfusion Dependence No and Platelet Count > 200X10E9/L	8	7	15
RBC Transfusion Independent Rate at Week 24			
Responder, n(%)	4 (50.0%)	3 (42.9%)	7 (46.7%)
95% Exact CI	0.1570, 0.8430	0.0990, 0.8159	0.2127, 0.7341
Proportion Difference (95% CI)	0.07 (-0.47, 0.61)		
Proportion Difference using Exact Method (95% CI)	0.07 (-0.44, 0.56)		
Non-Responder, n(%)	4 (50.0%)	4 (57.1%)	8 (53.3%)
Transfusion (except bleeding) in the last 12 weeks	1 (12.5%)	4 (57.1%)	5 (33.3%)
Any Hgb assessment < 8g/dL in the last 12 weeks	0	2 (28.6%)	2 (13.3%)
Last Participation date < Day 162 in DB phase	3 (37.5%)	0	3 (20.0%)
Other	0	2 (28.6%)	2 (13.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

Table 2.2802: Analysis of RBC Transfusion Independence Response Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are Not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
RBC Transfusion Independent Rate at Week 12			
Responder, n(%)	3 (37.5%)	2 (28.6%)	5 (33.3%)
95% Exact CI	0.0852, 0.7551	0.0367, 0.7096	0.1182, 0.6162
Proportion Difference (95% CI)	0.09 (-0.43, 0.61)		
Proportion Difference using Exact Method (95% CI)	0.09 (-0.41, 0.57)		
Non-Responder, n(%)	5 (62.5%)	5 (71.4%)	10 (66.7%)
Transfusion (except bleeding) in the last 12 weeks	5 (62.5%)	5 (71.4%)	10 (66.7%)
Any Hgb assessment < 8g/dL in the last 12 weeks	1 (12.5%)	4 (57.1%)	5 (33.3%)
Last Participation date < Day 78 in DB phase	0	0	0
Other	0	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

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Table 2.2801: Analysis of RBC Transfusion Independence Response Rate at Week 24 and Week 12

Double-Blind Phase

ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=25)	RUX (N=41)	Total (N=66)
All Strata Combined			
RBC Transfusion Independent Rate at Week 24			
Responder, n(%)	18 (72.0%)	14 (34.1%)	32 (48.5%)
95% Exact CI	0.5061, 0.8793	0.2008, 0.5059	0.3599, 0.6112
Proportion Difference - Stratified CMH Method (95% CI)	0.39 (0.15, 0.63)		
p-value	0.002		
Proportion Difference - Unstratified CMH Method (95% CI)	0.38 (0.14, 0.61)		
p-value	0.001		
Proportion Difference - Unstratified Exact Method (95% CI)	0.38 (0.13, 0.59)		
p-value	0.005		
Unadjusted Inverse Relative Risk (95% CI)	0.47 (0.29, 0.77)		
p-value [1]	0.003		
Unadjusted Inverse Odds Ratio (95% CI)	0.20 (0.07, 0.60)		
p-value [1]	0.004		
Unadjusted Absolute Risk Difference (95% CI)	0.38 (0.15, 0.61)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.47 (0.28, 0.77)		
p-value [2]	0.003		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel.

RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Table 2.2801: Analysis of RBC Transfusion Independence Response Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=25)	RUX (N=41)	Total (N=66)
Non-Responder, n(%)	7 (28.0%)	27 (65.9%)	34 (51.5%)
Transfusion (except bleeding) in the last 12 weeks	2 (8.0%)	23 (56.1%)	25 (37.9%)
Any Hgb assessment < 8g/dL in the last 12 weeks	3 (12.0%)	18 (43.9%)	21 (31.8%)
Last Participation date < Day 162 in DB phase	4 (16.0%)	1 (2.4%)	5 (7.6%)
Other	1 (4.0%)	8 (19.5%)	9 (13.6%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

Table 2.2801: Analysis of RBC Transfusion Independence Response Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=25)	RUX (N=41)	Total (N=66)
RBC Transfusion Independent Rate at Week 12			
Responder, n(%)	21 (84.0%)	14 (34.1%)	35 (53.0%)
95% Exact CI	0.6392, 0.9546	0.2008, 0.5059	0.4034, 0.6544
Proportion Difference - Stratified CMH Method (95% CI)	0.52 (0.30, 0.74)		
p-value	<0.001		
Proportion Difference - Unstratified CMH Method (95% CI)	0.50 (0.29, 0.71)		
p-value	<0.001		
Proportion Difference - Unstratified Exact Method (95% CI)	0.50 (0.26, 0.69)		
p-value	<0.001		
Unadjusted Inverse Relative Risk (95% CI)	0.41 (0.26, 0.64)		
p-value [1]	<0.001		
Unadjusted Inverse Odds Ratio (95% CI)	0.10 (0.03, 0.34)		
p-value [1]	<0.001		
Unadjusted Absolute Risk Difference (95% CI)	0.50 (0.29, 0.70)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.39 (0.25, 0.62)		
p-value [2]	<0.001		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

Table 2.2801: Analysis of RBC Transfusion Independence Response Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=25)	RUX (N=41)	Total (N=66)
Non-Responder, n(%)	4 (16.0%)	27 (65.9%)	31 (47.0%)
Transfusion (except bleeding) in the last 12 weeks	0	24 (58.5%)	24 (36.4%)
Any Hgb assessment < 8g/dL in the last 12 weeks	0	24 (58.5%)	24 (36.4%)
Last Participation date < Day 78 in DB phase	3 (12.0%)	0	3 (4.5%)
Other	1 (4.0%)	2 (4.9%)	3 (4.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

Table 2.2801: Analysis of RBC Transfusion Independence Response Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=25)	RUX (N=41)	Total (N=66)
Stratum 4			
Transfusion Dependence No and Platelet Count < 100X10E9/L	1	3	4
RBC Transfusion Independent Rate at Week 24			
Responder, n(%)	1 (100.0%)	0	1 (25.0%)
95% Exact CI	0.0250, 1.0000	0.0000, 0.7076	0.0063, 0.8059
Proportion Difference (95% CI)	1.00 (NA, NA)		
Proportion Difference using Exact Method (95% CI)	1.00 (-0.30, 1.00)		
Non-Responder, n(%)	0	3 (100.0%)	3 (75.0%)
Transfusion (except bleeding) in the last 12 weeks	0	1 (33.3%)	1 (25.0%)
Any Hgb assessment < 8g/dL in the last 12 weeks	0	1 (33.3%)	1 (25.0%)
Last Participation date < Day 162 in DB phase	0	1 (33.3%)	1 (25.0%)
Other	0	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Table 2.2801: Analysis of RBC Transfusion Independence Response Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=25)	RUX (N=41)	Total (N=66)
RBC Transfusion Independent Rate at Week 12			
Responder, n(%)	1 (100.0%)	1 (33.3%)	2 (50.0%)
95% Exact CI	0.0250, 1.0000	0.0084, 0.9057	0.0676, 0.9324
Proportion Difference (95% CI)	0.67 (NA, NA)		
Proportion Difference using Exact Method (95% CI)	0.67 (-0.59, 0.99)		
Non-Responder, n(%)	0	2 (66.7%)	2 (50.0%)
Transfusion (except bleeding) in the last 12 weeks	0	2 (66.7%)	2 (50.0%)
Any Hgb assessment < 8g/dL in the last 12 weeks	0	2 (66.7%)	2 (50.0%)
Last Participation date < Day 78 in DB phase	0	0	0
Other	0	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Table 2.2801: Analysis of RBC Transfusion Independence Response Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=25)	RUX (N=41)	Total (N=66)
Stratum 5			
Transfusion Dependence No and Platelet Count >= 100X10E9/L and <= 200X10E9/L	**14**	**14**	**28**
RBC Transfusion Independent Rate at Week 24			
Responder, n(%)	**10 (71.4%)**	**4 (28.6%)**	**14 (50.0%)**
95% Exact CI	**0.4190, 0.9161**	**0.0839, 0.5810**	**0.3065, 0.6935**
Proportion Difference (95% CI)	**0.43 (0.08, 0.78)**		
Proportion Difference using Exact Method (95% CI)	**0.43 (0.03, 0.74)**		
Non-Responder, n(%)	**4 (28.6%)**	**10 (71.4%)**	**14 (50.0%)**
Transfusion (except bleeding) in the last 12 weeks	**1 (7.1%)**	**9 (64.3%)**	**10 (35.7%)**
Any Hgb assessment < 8g/dL in the last 12 weeks	**2 (14.3%)**	**6 (42.9%)**	**8 (28.6%)**
Last Participation date < Day 162 in DB phase	**2 (14.3%)**	**0**	**2 (7.1%)**
Other	**1 (7.1%)**	**3 (21.4%)**	**4 (14.3%)**

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Table 2.2801: Analysis of RBC Transfusion Independence Response Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=25)	RUX (N=41)	Total (N=66)
RBC Transfusion Independent Rate at Week 12			
Responder, n(%)	12 (85.7%)	3 (21.4%)	15 (53.6%)
95% Exact CI	0.5719, 0.9822	0.0466, 0.5080	0.3387, 0.7249
Proportion Difference (95% CI)	0.64 (0.34, 0.95)		
Proportion Difference using Exact Method (95% CI)	0.64 (0.26, 0.88)		
Non-Responder, n(%)	2 (14.3%)	11 (78.6%)	13 (46.4%)
Transfusion (except bleeding) in the last 12 weeks	0	9 (64.3%)	9 (32.1%)
Any Hgb assessment < 8g/dL in the last 12 weeks	0	9 (64.3%)	9 (32.1%)
Last Participation date < Day 78 in DB phase	1 (7.1%)	0	1 (3.6%)
Other	1 (7.1%)	1 (7.1%)	2 (7.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-rbcti24-gba.sas V.03.05 Output file: t-rbcti24-ti-gba.pdf 29AUG2023: 9:36

Table 2.2801: Analysis of RBC Transfusion Independence Response Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=25)	RUX (N=41)	Total (N=66)
Stratum 6			
Transfusion Dependence No and Platelet Count > 200X10E9/L	10	24	34
RBC Transfusion Independent Rate at Week 24			
Responder, n(%)	7 (70.0%)	10 (41.7%)	17 (50.0%)
95% Exact CI	0.3475, 0.9333	0.2211, 0.6336	0.3243, 0.6757
Proportion Difference (95% CI)	0.28 (-0.08, 0.65)		
Proportion Difference using Exact Method (95% CI)	0.28 (-0.10, 0.61)		
Non-Responder, n(%)	3 (30.0%)	14 (58.3%)	17 (50.0%)
Transfusion (except bleeding) in the last 12 weeks	1 (10.0%)	13 (54.2%)	14 (41.2%)
Any Hgb assessment < 8g/dL in the last 12 weeks	1 (10.0%)	11 (45.8%)	12 (35.3%)
Last Participation date < Day 162 in DB phase	2 (20.0%)	0	2 (5.9%)
Other	0	5 (20.8%)	5 (14.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

Table 2.2801: Analysis of RBC Transfusion Independence Response Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=25)	RUX (N=41)	Total (N=66)
RBC Transfusion Independent Rate at Week 12			
Responder, n(%)	8 (80.0%)	10 (41.7%)	18 (52.9%)
95% Exact CI	0.4439, 0.9748	0.2211, 0.6336	0.3513, 0.7022
Proportion Difference (95% CI)	0.38 (0.04, 0.72)		
Proportion Difference using Exact Method (95% CI)	0.38 (0.01, 0.69)		
Non-Responder, n(%)	2 (20.0%)	14 (58.3%)	16 (47.1%)
Transfusion (except bleeding) in the last 12 weeks	0	13 (54.2%)	13 (38.2%)
Any Hgb assessment < 8g/dL in the last 12 weeks	0	13 (54.2%)	13 (38.2%)
Last Participation date < Day 78 in DB phase	2 (20.0%)	0	2 (5.9%)
Other	0	1 (4.2%)	1 (2.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

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Table 2.2902: Analysis of Rate of RBC Transfusion Independence by Week 24 by Age
Double-blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
RBC Transfusion Independent Rate by Week 24					
Responder, n(%)	13 (54.2%)	14 (38.9%)	34 (54.8%)	17 (29.3%)	
95% Exact CI	0.3282, 0.7445	0.2314, 0.5654	0.4168, 0.6752	0.1809, 0.4273	
Proportion Difference - Stratified CMH Method (95% CI)	0.17 (-0.12, 0.47)		0.30 (0.13, 0.47)		
p-value	0.25		<0.001		
Proportion Difference - Unstratified CMH Method (95% CI)	0.15 (-0.11, 0.41)		0.26 (0.08, 0.43)		
p-value	0.25		0.004		
Proportion Difference - Unstratified Exact Method (95% CI)	0.15 (-0.11, 0.40)		0.26 (0.08, 0.42)		
p-value	0.30		0.006		
Unadjusted Inverse Relative Risk (95% CI)	0.72 (0.41, 1.25)		0.53 (0.34, 0.85)		
p-value [1]	0.24		0.007		
Unadjusted interaction test for Treatment*Age Group [3]					0.42
Unadjusted Inverse Odds Ratio (95% CI)	0.54 (0.19, 1.53)		0.34 (0.16, 0.73)		
p-value [1]	0.25		0.005		
Unadjusted Absolute Risk Difference (95% CI)	0.15 (-0.10, 0.41)		0.26 (0.08, 0.43)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.68 (0.39, 1.19)		0.49 (0.31, 0.75)		
p-value [2]	0.17		0.001		
Adjusted interaction test for Treatment*Age Group [3]					0.32
Non-Responder, n(%)	11 (45.8%)	22 (61.1%)	28 (45.2%)	41 (70.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbcti-by24-gba.sas V.03.05 Output file: t-rbcti-by24-gba-age.pdf 24AUG2023:12:42

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Table 2.2908: Analysis of Rate of RBC Transfusion Independence by Week 24 by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
RBC Transfusion Independent Rate by Week 24				
Responder, n(%)	35 (59.3%)	21 (38.9%)	6 (37.5%)	8 (28.6%)
95% Exact CI	0.4575, 0.7193	0.2592, 0.5312	0.1520, 0.6457	0.1322, 0.4867
Proportion Difference - Stratified CMH Method (95% CI)	0.21 (0.03, 0.39)		0.14 (-0.13, 0.41)	
p-value	0.020		0.32	
Proportion Difference - Unstratified CMH Method (95% CI)	0.20 (0.02, 0.39)		0.09 (-0.21, 0.39)	
p-value	0.028		0.56	
Proportion Difference - Unstratified Exact Method (95% CI)	0.20 (0.02, 0.38)		0.09 (-0.22, 0.39)	
p-value	0.039		0.74	
Unadjusted Inverse Relative Risk (95% CI)	0.66 (0.44, 0.97)		0.76 (0.32, 1.80)	
p-value [1]	0.036		0.54	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.44 (0.21, 0.93)		0.67 (0.18, 2.45)	
p-value [1]	0.031		0.54	
Unadjusted Absolute Risk Difference (95% CI)	0.20 (0.02, 0.38)		0.09 (-0.20, 0.38)	
Adjusted Inverse Relative Risk (95% CI) [2]	0.65 (0.44, 0.95)		NE	
p-value [2]	0.025		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	24 (40.7%)	33 (61.1%)	10 (62.5%)	20 (71.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019

Table 2.2908: Analysis of Rate of RBC Transfusion Independence by Week 24 by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	RUX (N=12)	p-value
RBC Transfusion Independent Rate by Week 24			
Responder, n(%)	6 (54.5%)	2 (16.7%)	
95% Exact CI	0.2338, 0.8325	0.0209, 0.4841	
Proportion Difference - Stratified CMH Method (95% CI)	0.50 (0.09, 0.91)		
p-value	0.016		
Proportion Difference - Unstratified CMH Method (95% CI)	0.38 (-0.01, 0.77)		
p-value	0.055		
Proportion Difference - Unstratified Exact Method (95% CI)	0.38 (-0.06, 0.71)		
p-value	0.089		
Unadjusted Inverse Relative Risk (95% CI)	0.31 (0.08, 1.21)		
p-value [1]	0.091		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.44
Unadjusted Inverse Odds Ratio (95% CI)	0.17 (0.02, 1.14)		
p-value [1]	0.068		
Unadjusted Absolute Risk Difference (95% CI)	0.38 (0.02, 0.74)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.16
Non-Responder, n(%)	5 (45.5%)	10 (83.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbcti-by24-gba.sas V.03.05 Output file: t-rbcti-by24-gba-dstat.pdf 24AUG2023:12:42

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Table 2.2907: Analysis of Rate of RBC Transfusion Independence by Week 24 by Baseline Hemoglobin Level

Double-blind Phase

ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
RBC Transfusion Independent Rate by Week 24					
Responder, n(%)	10 (35.7%)	3 (14.3%)	37 (63.8%)	28 (38.4%)	
95% Exact CI	0.1864, 0.5593	0.0305, 0.3634	0.5012, 0.7601	0.2721, 0.5048	
Proportion Difference - Stratified CMH Method (95% CI)	0.22 (-0.04, 0.47)		0.28 (0.10, 0.45)		
p-value	0.099		0.002		
Proportion Difference - Unstratified CMH Method (95% CI)	0.21 (-0.03, 0.46)		0.25 (0.09, 0.42)		
p-value	0.083		0.003		
Proportion Difference - Unstratified Exact Method (95% CI)	0.21 (-0.07, 0.48)		0.25 (0.08, 0.42)		
p-value	0.11		0.005		
Unadjusted Inverse Relative Risk (95% CI)	0.40 (0.13, 1.28)		0.60 (0.42, 0.85)		
p-value [1]	0.12		0.004		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.47
Unadjusted Inverse Odds Ratio (95% CI)	0.30 (0.07, 1.27)		0.35 (0.17, 0.72)		
p-value [1]	0.10		0.004		
Unadjusted Absolute Risk Difference (95% CI)	0.21 (-0.02, 0.45)		0.25 (0.09, 0.42)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.40 (0.12, 1.27)		0.58 (0.41, 0.81)		
p-value [2]	0.12		0.001		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.52
Non-Responder, n(%)	18 (64.3%)	18 (85.7%)	21 (36.2%)	45 (61.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

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Table 2.2906: Analysis of Rate of RBC Transfusion Independence by Week 24 by Baseline IPSS Two-Level Risk

Double-blind Phase

ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
RBC Transfusion Independent Rate by Week 24					
Responder, n(%)	15 (53.6%)	8 (33.3%)	32 (55.2%)	23 (32.9%)	
95% Exact CI	0.3387, 0.7249	0.1563, 0.5532	0.4154, 0.6826	0.2209, 0.4512	
Proportion Difference - Stratified CMH Method (95% CI)	0.31 (0.02, 0.60)		0.25 (0.08, 0.42)		
p-value	0.038		0.004		
Proportion Difference - Unstratified CMH Method (95% CI)	0.20 (-0.07, 0.47)		0.22 (0.05, 0.39)		
p-value	0.14		0.010		
Proportion Difference - Unstratified Exact Method (95% CI)	0.20 (-0.07, 0.46)		0.22 (0.05, 0.39)		
p-value	0.17		0.013		
Unadjusted Inverse Relative Risk (95% CI)	0.62 (0.32, 1.21)		0.60 (0.40, 0.90)		
p-value [1]	0.16		0.013		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.91
Unadjusted Inverse Odds Ratio (95% CI)	0.43 (0.14, 1.34)		0.40 (0.19, 0.82)		
p-value [1]	0.15		0.012		
Unadjusted Absolute Risk Difference (95% CI)	0.20 (-0.06, 0.47)		0.22 (0.05, 0.39)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.50 (0.29, 0.87)		0.56 (0.37, 0.83)		
p-value [2]	0.014		0.004		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.93
Non-Responder, n(%)	13 (46.4%)	16 (66.7%)	26 (44.8%)	47 (67.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

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Table 2.2905: Analysis of Rate of RBC Transfusion Independence by Week 24 by Baseline IPSS Three-Level Risk

Double-blind Phase

ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
RBC Transfusion Independent Rate by Week 24				
Responder, n(%)	2 (100.0%)	2 (50.0%)	13 (50.0%)	6 (30.0%)
95% Exact CI	0.1581, 1.0000	0.0676, 0.9324	0.2993, 0.7007	0.1189, 0.5428
Proportion Difference - Stratified CMH Method (95% CI)	0.00 (-1.03, 1.03)		0.30 (0.01, 0.59)	
p-value	1.00		0.045	
Proportion Difference - Unstratified CMH Method (95% CI)	0.50 (-0.42, 1.42)		0.20 (-0.09, 0.49)	
p-value	0.29		0.17	
Proportion Difference - Unstratified Exact Method (95% CI)	0.50 (-0.45, 0.99)		0.20 (-0.10, 0.47)	
p-value	0.47		0.23	
Unadjusted Inverse Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	0	2 (50.0%)	13 (50.0%)	14 (70.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.2905: Analysis of Rate of RBC Transfusion Independence by Week 24 by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N=58)	RUX (N=70)	p-value
RBC Transfusion Independent Rate by Week 24			
Responder, n(%)	32 (55.2%)	23 (32.9%)	
95% Exact CI	0.4154, 0.6826	0.2209, 0.4512	
Proportion Difference - Stratified CMH Method (95% CI)	0.25 (0.08, 0.42)		
p-value	0.004		
Proportion Difference - Unstratified CMH Method (95% CI)	0.22 (0.05, 0.39)		
p-value	0.010		
Proportion Difference - Unstratified Exact Method (95% CI)	0.22 (0.05, 0.39)		
p-value	0.013		
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	26 (44.8%)	47 (67.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbcti-by24-gba.sas V.03.05 Output file: t-rbcti-by24-gba-ip3.pdf 24AUG2023:12:42

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Table 2.3002: Analysis of Rate of RBC Transfusion Independence by Week 24

Double-Blind Phase

ITT-Anemic Analysis Set Who are Not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
RBC Transfusion Independent Rate by Week 24			
Responder, n(%)	26 (42.6%)	11 (20.8%)	37 (32.5%)
95% Exact CI	0.3004, 0.5594	0.1084, 0.3411	0.2399, 0.4186
Proportion Difference - Stratified CMH Method (95% CI)	0.22 (0.05, 0.39)		
p-value	0.013		
Proportion Difference - Unstratified CMH Method (95% CI)	0.22 (0.05, 0.39)		
p-value	0.010		
Proportion Difference - Unstratified Exact Method (95% CI)	0.22 (0.03, 0.39)		
p-value	0.016		
Unadjusted Inverse Relative Risk (95% CI)	0.49 (0.27, 0.89)		
p-value [1]	0.019		
Unadjusted Inverse Odds Ratio (95% CI)	0.35 (0.15, 0.81)		
p-value [1]	0.014		
Unadjusted Absolute Risk Difference (95% CI)	0.22 (0.05, 0.38)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.49 (0.27, 0.88)		
p-value [2]	0.016		
Non-Responder, n(%)	35 (57.4%)	42 (79.2%)	77 (67.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel.

RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

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Table 2.2904: Analysis of Rate of RBC Transfusion Independence by Week 24 by Region
Double-blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
RBC Transfusion Independent Rate by Week 24					
Responder, n(%)	26 (49.1%)	16 (31.4%)	21 (63.6%)	15 (34.9%)	
95% Exact CI	0.3506, 0.6316	0.1911, 0.4589	0.4512, 0.7960	0.2101, 0.5093	
Proportion Difference - Stratified CMH Method (95% CI)	0.25 (0.06, 0.44)		0.30 (0.08, 0.53)		
p-value	0.009		0.008		
Proportion Difference - Unstratified CMH Method (95% CI)	0.18 (-0.01, 0.36)		0.29 (0.07, 0.51)		
p-value	0.064		0.011		
Proportion Difference - Unstratified Exact Method (95% CI)	0.18 (-0.01, 0.36)		0.29 (0.06, 0.49)		
p-value	0.075		0.020		
Unadjusted Inverse Relative Risk (95% CI)	0.64 (0.39, 1.04)		0.55 (0.34, 0.89)		
p-value [1]	0.074		0.015		
Unadjusted interaction test for Treatment*Region [3]					0.66
Unadjusted Inverse Odds Ratio (95% CI)	0.47 (0.21, 1.06)		0.31 (0.12, 0.79)		
p-value [1]	0.068		0.014		
Unadjusted Absolute Risk Difference (95% CI)	0.18 (-0.01, 0.36)		0.29 (0.07, 0.50)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.53 (0.33, 0.83)		0.52 (0.32, 0.85)		
p-value [2]	0.006		0.008		
Adjusted interaction test for Treatment*Region [3]					0.97
Non-Responder, n(%)	27 (50.9%)	35 (68.6%)	12 (36.4%)	28 (65.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbcti-by24-gba.sas V.03.05 Output file: t-rbcti-by24-gba-reg.pdf 24AUG2023:12:42

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Table 2.2903: Analysis of Rate of RBC Transfusion Independence by Week 24 by Gender

Double-blind Phase

ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
RBC Transfusion Independent Rate by Week 24					
Responder, n(%)	25 (50.0%)	19 (33.9%)	22 (61.1%)	12 (31.6%)	
95% Exact CI	0.3553, 0.6447	0.2181, 0.4781	0.4346, 0.7686	0.1750, 0.4865	
Proportion Difference - Stratified CMH Method (95% CI)	0.23 (0.05, 0.42)		0.27 (0.03, 0.51)		
p-value	0.013		0.030		
Proportion Difference - Unstratified CMH Method (95% CI)	0.16 (-0.03, 0.35)		0.30 (0.07, 0.52)		
p-value	0.094		0.009		
Proportion Difference - Unstratified Exact Method (95% CI)	0.16 (-0.03, 0.34)		0.30 (0.06, 0.50)		
p-value	0.12		0.019		
Unadjusted Inverse Relative Risk (95% CI)	0.68 (0.43, 1.07)		0.52 (0.30, 0.88)		
p-value [1]	0.098		0.016		
Unadjusted interaction test for Treatment*Gender [3]					0.44
Unadjusted Inverse Odds Ratio (95% CI)	0.51 (0.23, 1.12)		0.29 (0.11, 0.77)		
p-value [1]	0.095		0.012		
Unadjusted Absolute Risk Difference (95% CI)	0.16 (-0.03, 0.35)		0.30 (0.08, 0.51)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.56 (0.37, 0.87)		0.55 (0.33, 0.94)		
p-value [2]	0.010		0.027		
Adjusted interaction test for Treatment*Gender [3]					0.83
Non-Responder, n(%)	25 (50.0%)	37 (66.1%)	14 (38.9%)	26 (68.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

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Table 2.2910: Analysis of Rate of RBC Transfusion Independence by Week 24 by Baseline Spleen Volume

Double-blind Phase

ITT-Anemic Analysis Set

	<Median (1837.09 cm^3)		>=Median (1837.09 cm^3)		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
RBC Transfusion Independent Rate by Week 24					
Responder, n(%)	29 (61.7%)	10 (23.3%)	18 (46.2%)	21 (41.2%)	
95% Exact CI	0.4638, 0.7549	0.1176, 0.3863	0.3009, 0.6282	0.2758, 0.5583	
Proportion Difference - Stratified CMH Method (95% CI)	0.43 (0.23, 0.64)		0.14 (-0.07, 0.34)		
p-value	<0.001		0.19		
Proportion Difference - Unstratified CMH Method (95% CI)	0.38 (0.19, 0.58)		0.05 (-0.16, 0.26)		
p-value	<0.001		0.64		
Proportion Difference - Unstratified Exact Method (95% CI)	0.38 (0.18, 0.56)		0.05 (-0.16, 0.26)		
p-value	<0.001		0.67		
Unadjusted Inverse Relative Risk (95% CI)	0.38 (0.21, 0.68)		0.89 (0.56, 1.43)		
p-value [1]	0.001		0.64		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.019
Unadjusted Inverse Odds Ratio (95% CI)	0.19 (0.07, 0.47)		0.82 (0.35, 1.89)		
p-value [1]	<0.001		0.64		
Unadjusted Absolute Risk Difference (95% CI)	0.38 (0.20, 0.57)		0.05 (-0.16, 0.26)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.33 (0.18, 0.61)		0.73 (0.48, 1.12)		
p-value [2]	<0.001		0.15		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.025
Non-Responder, n(%)	18 (38.3%)	33 (76.7%)	21 (53.8%)	30 (58.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

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Table 2.3001: Analysis of Rate of RBC Transfusion Independence by Week 24

Double-Blind Phase

ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=25)	RUX (N=41)	Total (N=66)
RBC Transfusion Independent Rate by Week 24			
Responder, n(%)	21 (84.0%)	20 (48.8%)	41 (62.1%)
95% Exact CI	0.6392, 0.9546	0.3288, 0.6487	0.4934, 0.7378
Proportion Difference - Stratified CMH Method (95% CI)	0.36 (0.13, 0.59)		
p-value	0.002		
Proportion Difference - Unstratified CMH Method (95% CI)	0.35 (0.14, 0.57)		
p-value	0.001		
Proportion Difference - Unstratified Exact Method (95% CI)	0.35 (0.10, 0.57)		
p-value	0.005		
Unadjusted Inverse Relative Risk (95% CI)	0.58 (0.41, 0.83)		
p-value [1]	0.003		
Unadjusted Inverse Odds Ratio (95% CI)	0.18 (0.05, 0.62)		
p-value [1]	0.007		
Unadjusted Absolute Risk Difference (95% CI)	0.35 (0.14, 0.56)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.57 (0.40, 0.83)		
p-value [2]	0.003		
Non-Responder, n(%)	4 (16.0%)	21 (51.2%)	25 (37.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel.

RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

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Table 2.2909: Analysis of Rate of RBC Transfusion Independence by Week 24 by Baseline TSS

Double-blind Phase

ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
RBC Transfusion Independent Rate by Week 24					
Responder, n(%)	26 (59.1%)	20 (36.4%)	20 (48.8%)	11 (28.9%)	
95% Exact CI	0.4325, 0.7366	0.2381, 0.5044	0.3288, 0.6487	0.1542, 0.4590	
Proportion Difference - Stratified CMH Method (95% CI)	0.28 (0.09, 0.48)		0.23 (0.02, 0.44)		
p-value	0.004		0.031		
Proportion Difference - Unstratified CMH Method (95% CI)	0.23 (0.03, 0.42)		0.20 (-0.02, 0.41)		
p-value	0.023		0.069		
Proportion Difference - Unstratified Exact Method (95% CI)	0.23 (0.03, 0.41)		0.20 (-0.02, 0.41)		
p-value	0.028		0.11		
Unadjusted Inverse Relative Risk (95% CI)	0.62 (0.40, 0.94)		0.59 (0.33, 1.07)		
p-value [1]	0.026		0.082		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.92
Unadjusted Inverse Odds Ratio (95% CI)	0.40 (0.18, 0.89)		0.43 (0.17, 1.09)		
p-value [1]	0.026		0.074		
Unadjusted Absolute Risk Difference (95% CI)	0.23 (0.03, 0.42)		0.20 (-0.01, 0.41)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.54 (0.36, 0.82)		0.54 (0.32, 0.92)		
p-value [2]	0.004		0.024		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.91
Non-Responder, n(%)	18 (40.9%)	35 (63.6%)	21 (51.2%)	27 (71.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

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Table 2.2901: Analysis of Rate of RBC Transfusion Independence by Week 24
Double-blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
RBC Transfusion Independent Rate by Week 24			
Responder, n(%)	47 (54.7%)	31 (33.0%)	78 (43.3%)
95% Exact CI	0.4355, 0.6542	0.2362, 0.4344	0.3598, 0.5091
Proportion Difference - Stratified CMH Method (95% CI)	0.25 (0.12, 0.39)		
p-value	<0.001		
Proportion Difference - Unstratified CMH Method (95% CI)	0.22 (0.07, 0.36)		
p-value	0.003		
Proportion Difference - Unstratified Exact Method (95% CI)	0.22 (0.07, 0.36)		
p-value	0.004		
Unadjusted Inverse Relative Risk (95% CI)	0.60 (0.43, 0.85)		
p-value [1]	0.004		
Unadjusted Inverse Odds Ratio (95% CI)	0.41 (0.22, 0.75)		
p-value [1]	0.004		
Unadjusted Absolute Risk Difference (95% CI)	0.22 (0.07, 0.36)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.55 (0.40, 0.77)		
p-value [2]	<0.001		
Non-Responder, n(%)	39 (45.3%)	63 (67.0%)	102 (56.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-rbcti-by24-gba.sas V.03.05 Output file: t-rbcti-by24-gba.pdf 24AUG2023:12:42

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Table 2.4202: Analysis of response rate of no Transfusion of Any Type for 24 weeks by Age
Double-blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Any Type Transfusion Free Rate					
Responder, n(%)	10 (41.7%)	12 (33.3%)	23 (37.1%)	7 (12.1%)	
95% Exact CI	0.2211, 0.6336	0.1856, 0.5097	0.2516, 0.5031	0.0499, 0.2330	
Proportion Difference - Unstratified Exact Method (95% CI)	0.08 (-0.18, 0.34)		0.25 (0.07, 0.42)		
p-value	0.59		0.002		
Unadjusted Inverse Relative Risk (95% CI)	0.80 (0.41, 1.55)		0.33 (0.15, 0.70)		
p-value [1]	0.51		0.004		
Unadjusted interaction test for Treatment*Age Group [3]					0.072
Unadjusted Inverse Odds Ratio (95% CI)	0.70 (0.24, 2.03)		0.23 (0.09, 0.60)		
p-value [1]	0.51		0.002		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.17, 0.33)		0.25 (0.10, 0.40)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.92 (0.47, 1.81)		NE		
p-value [2]	0.82		NE		
Adjusted interaction test for Treatment*Age Group [3]					0.034
Non-responder, n(%)	14 (58.3%)	24 (66.7%)	39 (62.9%)	51 (87.9%)	
Any Type Transfusion within 24 weeks	12 (50.0%)	24 (66.7%)	35 (56.5%)	50 (86.2%)	
Discontinued prior to week 24	2 (8.3%)	0	4 (6.5%)	1 (1.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-atf-for24-db-gba.sas V.03.05 Output file: t-sg-atf-for24-db-gba-age.pdf 24AUG2023:12:44

Table 2.4207: Analysis of response rate of no Transfusion of Any Type for 24 weeks by Baseline Hemoglobin Level
Double-blind Phase
ITT-Anemic Analysis Set

	HGB <8g/dL		HGB >=8g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Any Type Transfusion Free Rate					
Responder, n(%)	5 (17.9%)	2 (9.5%)	28 (48.3%)	17 (23.3%)	
95% Exact CI	0.0606, 0.3689	0.0117, 0.3038	0.3495, 0.6178	0.1419, 0.3465	
Proportion Difference - Unstratified Exact Method (95% CI)	0.08 (-0.20, 0.36)		0.25 (0.08, 0.41)		
p-value	0.68		0.003		
Unadjusted Inverse Relative Risk (95% CI)	0.53 (0.11, 2.49)		0.48 (0.29, 0.79)		
p-value [1]	0.42		0.004		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.91
Unadjusted Inverse Odds Ratio (95% CI)	0.48 (0.08, 2.78)		0.33 (0.15, 0.69)		
p-value [1]	0.42		0.003		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.11, 0.27)		0.25 (0.09, 0.41)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.55 (0.12, 2.55)		0.46 (0.29, 0.74)		
p-value [2]	0.44		0.001		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.83
Non-responder, n(%)	23 (82.1%)	19 (90.5%)	30 (51.7%)	56 (76.7%)	
Any Type Transfusion within 24 weeks	21 (75.0%)	19 (90.5%)	26 (44.8%)	55 (75.3%)	
Discontinued prior to week 24	2 (7.1%)	0	4 (6.9%)	1 (1.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

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Table 2.4206: Analysis of response rate of no Transfusion of Any Type for 24 weeks by Baseline IPSS Two-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Any Type Transfusion Free Rate					
Responder, n(%)	13 (46.4%)	7 (29.2%)	20 (34.5%)	12 (17.1%)	
95% Exact CI	0.2751, 0.6613	0.1262, 0.5109	0.2249, 0.4812	0.0918, 0.2803	
Proportion Difference - Unstratified Exact Method (95% CI)	0.17 (-0.10, 0.43)		0.17 (0.00, 0.34)		
p-value	0.26		0.039		
Unadjusted Inverse Relative Risk (95% CI)	0.63 (0.30, 1.32)		0.50 (0.27, 0.93)		
p-value [1]	0.22		0.028		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.64
Unadjusted Inverse Odds Ratio (95% CI)	0.48 (0.15, 1.50)		0.39 (0.17, 0.90)		
p-value [1]	0.21		0.026		
Unadjusted Absolute Risk Difference (95% CI)	0.17 (-0.09, 0.43)		0.17 (0.02, 0.32)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.74
Non-responder, n(%)	15 (53.6%)	17 (70.8%)	38 (65.5%)	58 (82.9%)	
Any Type Transfusion within 24 weeks	12 (42.9%)	17 (70.8%)	35 (60.3%)	57 (81.4%)	
Discontinued prior to week 24	3 (10.7%)	0	3 (5.2%)	1 (1.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-atf-for24-db-gba.sas V.03.05 Output file: t-sg-atf-for24-db-gba-ip2.pdf 24AUG2023:12:44

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Table 2.4205: Analysis of response rate of no Transfusion of Any Type for 24 weeks by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Any Type Transfusion Free Rate				
Responder, n(%)	2 (100.0%)	1 (25.0%)	11 (42.3%)	6 (30.0%)
95% Exact CI	0.1581, 1.0000	0.0063, 0.8059	0.2335, 0.6308	0.1189, 0.5428
Proportion Difference - Unstratified Exact Method (95% CI)	0.75 (-0.23, 0.99)		0.12 (-0.17, 0.40)	
p-value	0.40		0.54	
Unadjusted Inverse Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-responder, n(%)	0	3 (75.0%)	15 (57.7%)	14 (70.0%)
Any Type Transfusion within 24 weeks	0	3 (75.0%)	12 (46.2%)	14 (70.0%)
Discontinued prior to week 24	0	0	3 (11.5%)	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.4205: Analysis of response rate of no Transfusion of Any Type for 24 weeks by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=58)	High Risk RUX (N=70)	p-value
Any Type Transfusion Free Rate			
Responder, n(%)	20 (34.5%)	12 (17.1%)	
95% Exact CI	0.2249, 0.4812	0.0918, 0.2803	
Proportion Difference - Unstratified Exact Method (95% CI)	0.17 (0.00, 0.34)		
p-value	0.039		
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-responder, n(%)	38 (65.5%)	58 (82.9%)	
Any Type Transfusion within 24 weeks	35 (60.3%)	57 (81.4%)	
Discontinued prior to week 24	3 (5.2%)	1 (1.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

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Table 2.4208: Analysis of response rate of no Transfusion of Any Type for 24 weeks by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Any Type Transfusion Free Rate				
Responder, n(%)	23 (39.0%)	11 (20.4%)	5 (31.3%)	7 (25.0%)
95% Exact CI	0.2655, 0.5256	0.1063, 0.3353	0.1102, 0.5866	0.1069, 0.4487
Proportion Difference - Unstratified Exact Method (95% CI)	0.19 (0.00, 0.36)		0.06 (-0.25, 0.36)	
p-value	0.040		0.73	
Unadjusted Inverse Relative Risk (95% CI)	0.52 (0.28, 0.97)		0.80 (0.30, 2.11)	
p-value [1]	0.039		0.65	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.40 (0.17, 0.93)		0.73 (0.19, 2.86)	
p-value [1]	0.034		0.65	
Unadjusted Absolute Risk Difference (95% CI)	0.19 (0.02, 0.35)		0.06 (-0.22, 0.34)	
Adjusted Inverse Relative Risk (95% CI) [2]	0.52 (0.28, 0.94)		NE	
p-value [2]	0.032		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-responder, n(%)	36 (61.0%)	43 (79.6%)	11 (68.8%)	21 (75.0%)
Any Type Transfusion within 24 weeks	31 (52.5%)	42 (77.8%)	11 (68.8%)	21 (75.0%)
Discontinued prior to week 24	5 (8.5%)	1 (1.9%)	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-atf-for24-db-gba.sas V.03.05 Output file: t-sg-atf-for24-db-gba-mf.pdf 24AUG2023:12:44

Table 2.4208: Analysis of response rate of no Transfusion of Any Type for 24 weeks by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=11)	Post-PV Myelofibrosis RUX (N=12)	p-value
Any Type Transfusion Free Rate			
Responder, n(%)	5 (45.5%)	1 (8.3%)	
95% Exact CI	0.1675, 0.7662	0.0021, 0.3848	
Proportion Difference - Unstratified Exact Method (95% CI)	0.37 (-0.06, 0.70)		
p-value	0.069		
Unadjusted Inverse Relative Risk (95% CI)	0.18 (0.03, 1.33)		
p-value [1]	0.094		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.29
Unadjusted Inverse Odds Ratio (95% CI)	0.11 (0.01, 1.16)		
p-value [1]	0.066		
Unadjusted Absolute Risk Difference (95% CI)	0.37 (0.04, 0.70)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.11
Non-responder, n(%)	6 (54.5%)	11 (91.7%)	
Any Type Transfusion within 24 weeks	5 (45.5%)	11 (91.7%)	
Discontinued prior to week 24	1 (9.1%)	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-atf-for24-db-gba.sas V.03.05 Output file: t-sg-atf-for24-db-gba-mf.pdf 24AUG2023:12:44

Table 2.4204: Analysis of response rate of no Transfusion of Any Type for 24 weeks by Region
Double-blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Any Type Transfusion Free Rate					
Responder, n(%)	17 (32.1%)	9 (17.6%)	16 (48.5%)	10 (23.3%)	
95% Exact CI	0.1992, 0.4632	0.0840, 0.3087	0.3080, 0.6646	0.1176, 0.3863	
Proportion Difference - Unstratified Exact Method (95% CI)	0.14 (-0.05, 0.33)		0.25 (0.03, 0.46)		
p-value	0.11		0.029		
Unadjusted Inverse Relative Risk (95% CI)	0.55 (0.27, 1.12)		0.48 (0.25, 0.92)		
p-value [1]	0.099		0.026		
Unadjusted interaction test for Treatment*Region [3]					0.78
Unadjusted Inverse Odds Ratio (95% CI)	0.45 (0.18, 1.14)		0.32 (0.12, 0.86)		
p-value [1]	0.093		0.024		
Unadjusted Absolute Risk Difference (95% CI)	0.14 (-0.02, 0.31)		0.25 (0.04, 0.46)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.41 (0.21, 0.78)		NE		
p-value [2]	0.006		NE		
Adjusted interaction test for Treatment*Region [3]					0.92
Non-responder, n(%)	36 (67.9%)	42 (82.4%)	17 (51.5%)	33 (76.7%)	
Any Type Transfusion within 24 weeks	34 (64.2%)	42 (82.4%)	13 (39.4%)	32 (74.4%)	
Discontinued prior to week 24	2 (3.8%)	0	4 (12.1%)	1 (2.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.4203: Analysis of response rate of no Transfusion of Any Type for 24 weeks by Gender
Double-blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Any Type Transfusion Free Rate					
Responder, n(%)	16 (32.0%)	9 (16.1%)	17 (47.2%)	10 (26.3%)	
95% Exact CI	0.1952, 0.4670	0.0762, 0.2833	0.3041, 0.6451	0.1340, 0.4310	
Proportion Difference - Unstratified Exact Method (95% CI)	0.16 (-0.03, 0.34)		0.21 (-0.03, 0.42)		
p-value	0.068		0.091		
Unadjusted Inverse Relative Risk (95% CI)	0.50 (0.24, 1.03)		0.56 (0.30, 1.05)		
p-value [1]	0.062		0.071		
Unadjusted interaction test for Treatment*Gender [3]					0.83
Unadjusted Inverse Odds Ratio (95% CI)	0.41 (0.16, 1.03)		0.40 (0.15, 1.06)		
p-value [1]	0.058		0.065		
Unadjusted Absolute Risk Difference (95% CI)	0.16 (0.00, 0.32)		0.21 (-0.01, 0.42)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.38 (0.19, 0.76)		NE		
p-value [2]	0.006		NE		
Adjusted interaction test for Treatment*Gender [3]					0.37
Non-responder, n(%)	34 (68.0%)	47 (83.9%)	19 (52.8%)	28 (73.7%)	
Any Type Transfusion within 24 weeks	34 (68.0%)	47 (83.9%)	13 (36.1%)	27 (71.1%)	
Discontinued prior to week 24	0	0	6 (16.7%)	1 (2.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.4210: Analysis of response rate of no Transfusion of Any Type for 24 weeks by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Any Type Transfusion Free Rate					
Responder, n(%)	22 (46.8%)	8 (18.6%)	11 (28.2%)	11 (21.6%)	
95% Exact CI	0.3211, 0.6192	0.0839, 0.3340	0.1500, 0.4487	0.1129, 0.3532	
Proportion Difference - Unstratified Exact Method (95% CI)	0.28 (0.07, 0.47)		0.07 (-0.14, 0.27)		
p-value	0.007		0.62		
Unadjusted Inverse Relative Risk (95% CI)	0.40 (0.20, 0.80)		0.76 (0.37, 1.58)		
p-value [1]	0.009		0.47		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.20
Unadjusted Inverse Odds Ratio (95% CI)	0.26 (0.10, 0.68)		0.70 (0.27, 1.84)		
p-value [1]	0.006		0.47		
Unadjusted Absolute Risk Difference (95% CI)	0.28 (0.10, 0.47)		0.07 (-0.11, 0.25)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.69 (0.34, 1.40)		
p-value [2]	NE		0.30		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.32
Non-responder, n(%)	25 (53.2%)	35 (81.4%)	28 (71.8%)	40 (78.4%)	
Any Type Transfusion within 24 weeks	22 (46.8%)	34 (79.1%)	25 (64.1%)	40 (78.4%)	
Discontinued prior to week 24	3 (6.4%)	1 (2.3%)	3 (7.7%)	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.4209: Analysis of response rate of no Transfusion of Any Type for 24 weeks by Baseline TSS
Double-blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Any Type Transfusion Free Rate					
Responder, n(%)	18 (40.9%)	11 (20.0%)	15 (36.6%)	8 (21.1%)	
95% Exact CI	0.2634, 0.5675	0.1043, 0.3297	0.2212, 0.5306	0.0955, 0.3732	
Proportion Difference - Unstratified Exact Method (95% CI)	0.21 (0.01, 0.40)		0.16 (-0.07, 0.36)		
p-value	0.028		0.15		
Unadjusted Inverse Relative Risk (95% CI)	0.49 (0.26, 0.92)		0.58 (0.28, 1.20)		
p-value [1]	0.028		0.14		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.74
Unadjusted Inverse Odds Ratio (95% CI)	0.36 (0.15, 0.88)		0.46 (0.17, 1.26)		
p-value [1]	0.025		0.13		
Unadjusted Absolute Risk Difference (95% CI)	0.21 (0.03, 0.39)		0.16 (-0.04, 0.35)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.53 (0.27, 1.06)		
p-value [2]	NE		0.072		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.56
Non-responder, n(%)	26 (59.1%)	44 (80.0%)	26 (63.4%)	30 (78.9%)	
Any Type Transfusion within 24 weeks	24 (54.5%)	43 (78.2%)	22 (53.7%)	30 (78.9%)	
Discontinued prior to week 24	2 (4.5%)	1 (1.8%)	4 (9.8%)	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-atf-for24-db-gba.sas V.03.05 Output file: t-sg-atf-for24-db-gba-tss.pdf 24AUG2023:12:44

Table 2.3401: Analysis of Time to RBC Transfusion Independent Response
Double-blind Phase
ITT-Anemic Analysis Set who are not Transfusion Independent at baseline but at any Post-baseline

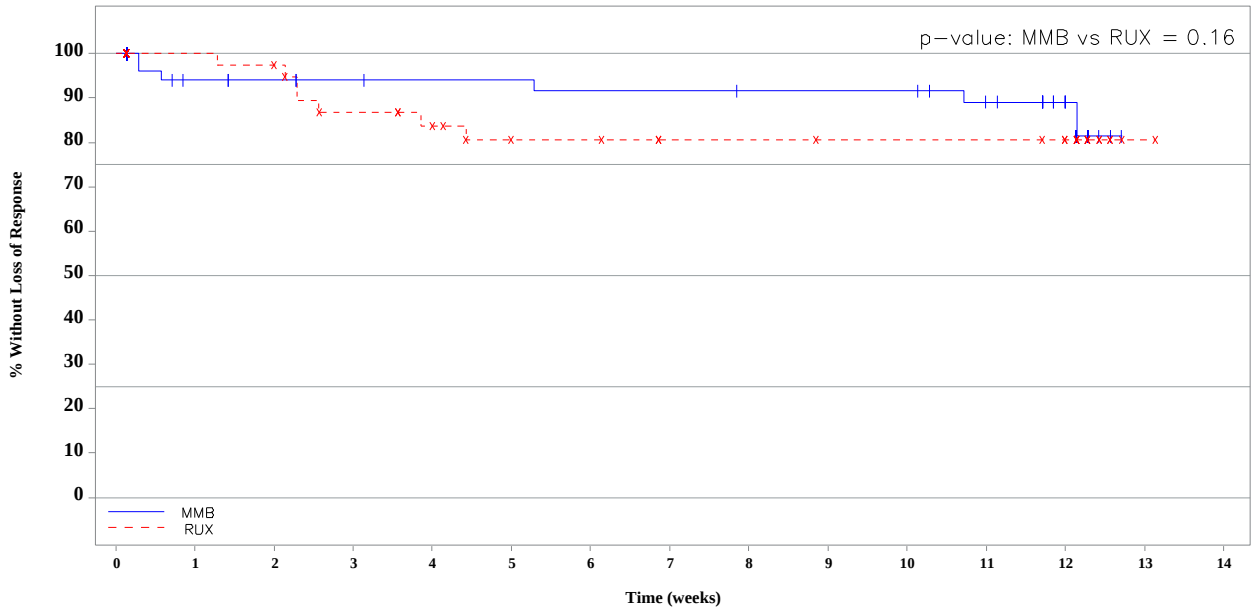
	MMB (N=26)	RUX (N=11)
Subjects with Event		
RBC Transfusion Independent Response, n(%)	26 (100.0%)	11 (100.0%)
Censor		
Subjects Censored, n(%)	0	0
Kaplan-Meier Estimate of Time to RBC Transfusion Independent Response (Weeks)		
25-percentile (95% CI)	12.14 (NE, NE)	12.14 (NE, NE)
Median (95% CI)	12.71 (12.14, 16.57)	12.14 (12.14, 20.00)
75-percentile (95% CI)	22.00 (13.14, 23.43)	20.00 (12.14, NE)
Min, Max	12.14, 24.14	12.14, 22.57
Stratified Log-Rank Test p-value	0.37	
Adjusted Inverse Hazard Ratio (95% CI)	1.61 (0.74, 3.49)	
Unstratified Log-Rank Test p-value	0.32	
Unadjusted Inverse Hazard Ratio (95% CI)	1.44 (0.69, 3.01)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio nd 95% CI are from a Cox proportional hazards model with a covariate of treatment. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-tte-ti.sas V.03.05 Output file: t-tte-ti-tib.pdf 24AUG2023:12:42

1.6.2 TF

Figure 2.2701: Kaplan-Meier Plot of Duration of Any Type Transfusion Free Response
Double-blind Phase
ITT-Anemic Analysis Set



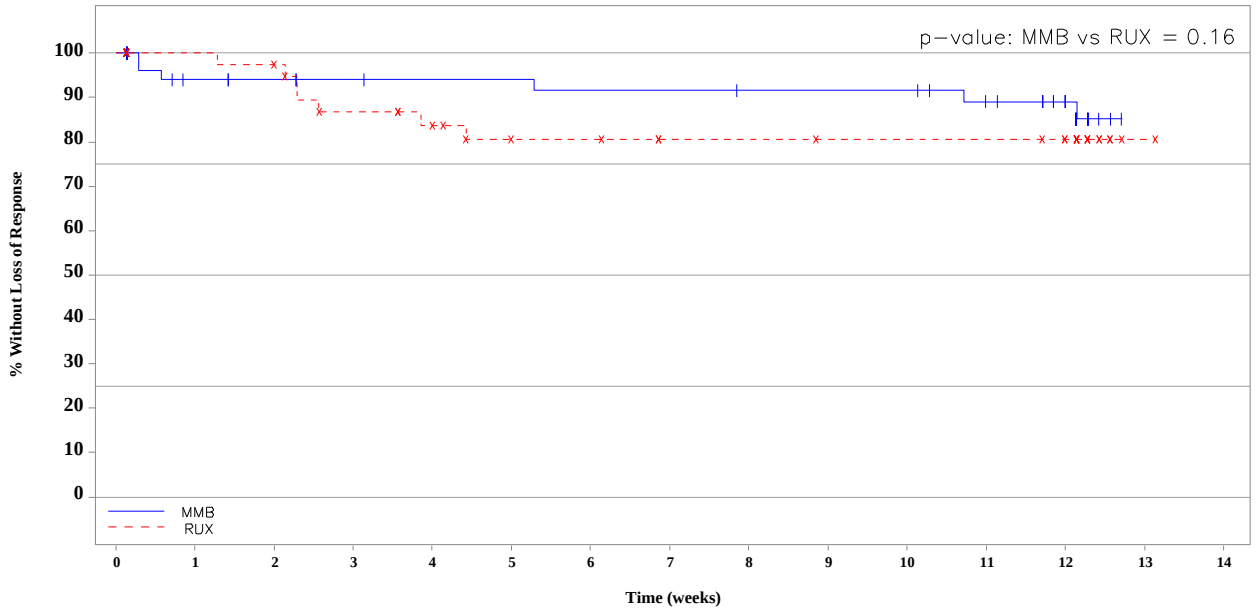
N at Risk (Events)

MMB	86 (0)	45 (3)	43 (3)	41 (3)	40 (3)	40 (3)	39 (4)	39 (4)	38 (4)	38 (4)	38 (4)	35 (5)	26 (5)	0 (7)	0 (7)
RUX	94 (0)	39 (0)	38 (1)	31 (5)	28 (6)	24 (7)	23 (7)	20 (7)	20 (7)	19 (7)	19 (7)	19 (7)	18 (7)	1 (7)	0 (7)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L).

Data Extracted: CRF data: 01JUL2019
Source: g-dur-any-tfr.sas V.03.05 Output file: g-dur-any-tfr.pdf 29AUG2023:15:20

Figure 2.1801: Kaplan-Meier Plot of Duration of RBC Transfusion Free Response
Double-blind Phase
ITT-Anemic Analysis Set



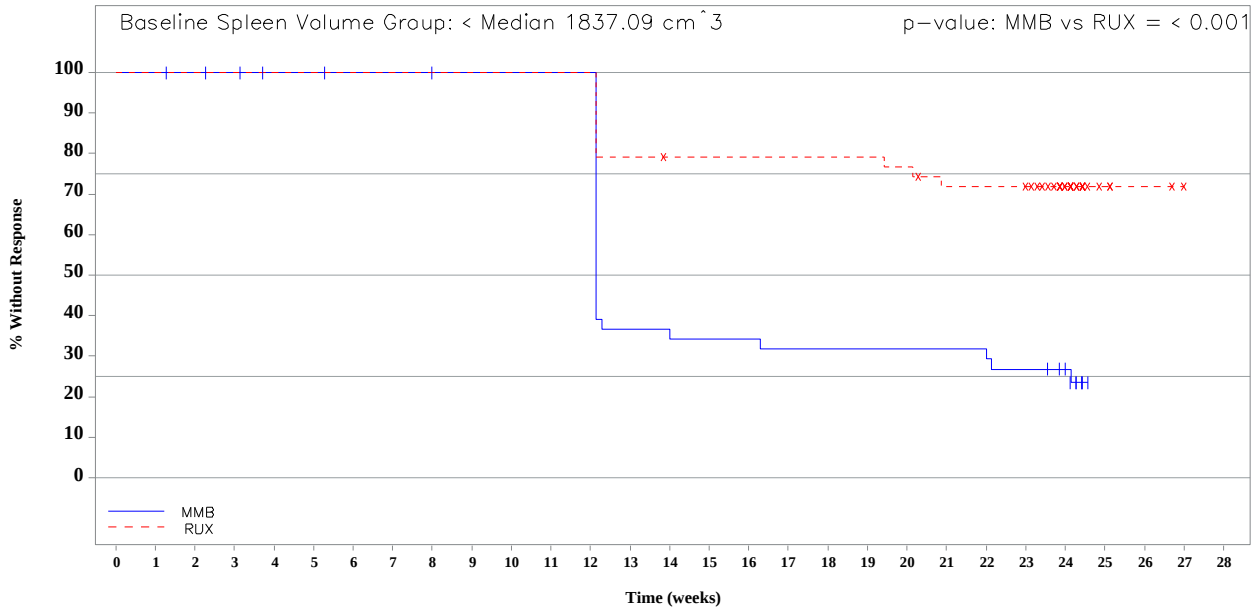
N at Risk (Events)

MMB	86 (0)	45 (3)	43 (3)	41 (3)	40 (3)	40 (3)	39 (4)	39 (4)	38 (4)	38 (4)	38 (4)	35 (5)	26 (5)	0 (6)	0 (6)
RUX	94 (0)	39 (0)	38 (1)	31 (5)	28 (6)	24 (7)	23 (7)	20 (7)	20 (7)	19 (7)	19 (7)	19 (7)	18 (7)	1 (7)	0 (7)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L).

Data Extracted: CRF data: 01JUL2019
Source: g-dur-rbc-tfr.sas V.03.05 Output file: g-dur-rbc-tfr.pdf 29AUG2023:15:19

Figure 2.2610: Kaplan-Meier Plot of Time to Any Type Transfusion Free Response by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set



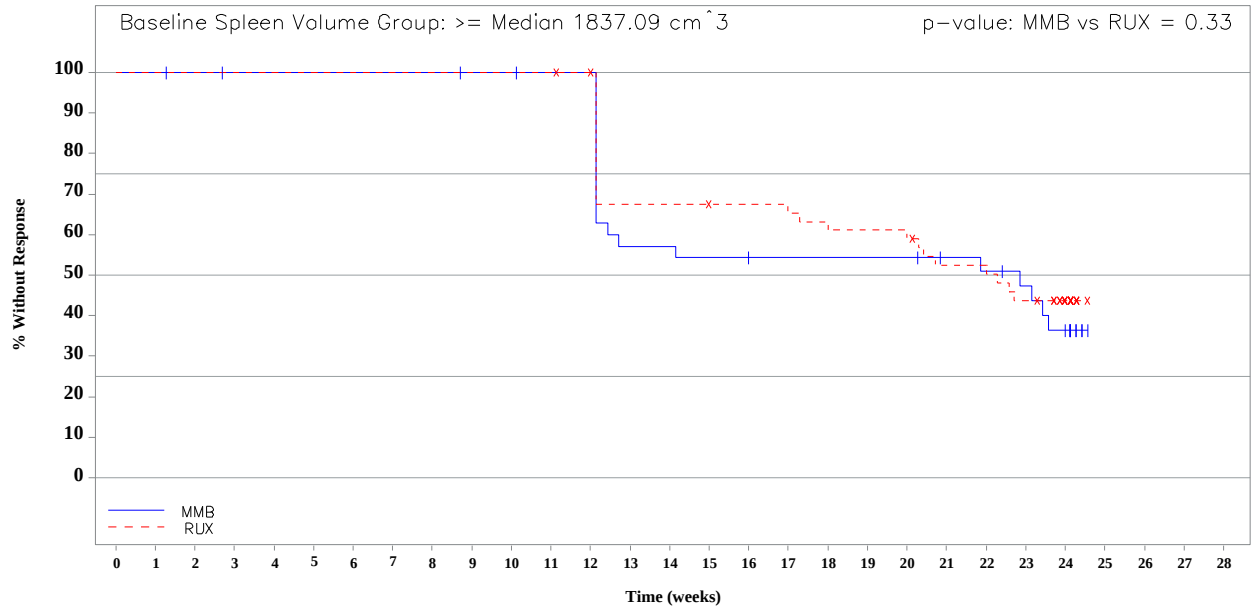
N at Risk (Events)

MMB	47 (0)	47 (0)	46 (0)	45 (0)	43 (0)	43 (0)	42 (0)	42 (0)	42 (0)	41 (0)	41 (0)	41 (0)	41 (0)	15 (26)	15 (27)	14 (27)	14 (27)	13 (28)	13 (28)	13 (28)	13 (28)	13 (28)	13 (29)	11 (30)	9 (30)	0 (31)	0 (31)	0 (31)	0 (31)
RUX	43 (0)	43 (0)	43 (0)	43 (0)	43 (0)	43 (0)	43 (0)	43 (0)	43 (0)	43 (0)	43 (0)	43 (0)	43 (0)	34 (9)	33 (9)	33 (9)	33 (9)	33 (9)	33 (9)	33 (9)	33 (9)	32 (10)	29 (12)	29 (12)	29 (12)	19 (12)	4 (12)	2 (12)	1 (12)	0 (12)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L).

Data Extracted: CRF data: 01JUL2019
Source: g-tte-any-tfr-sub.sas V.03.05 Output file: g-tte-any-tfr-svb.pdf 29AUG2023:15:20

Figure 2.2610: Kaplan-Meier Plot of Time to Any Type Transfusion Free Response by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set



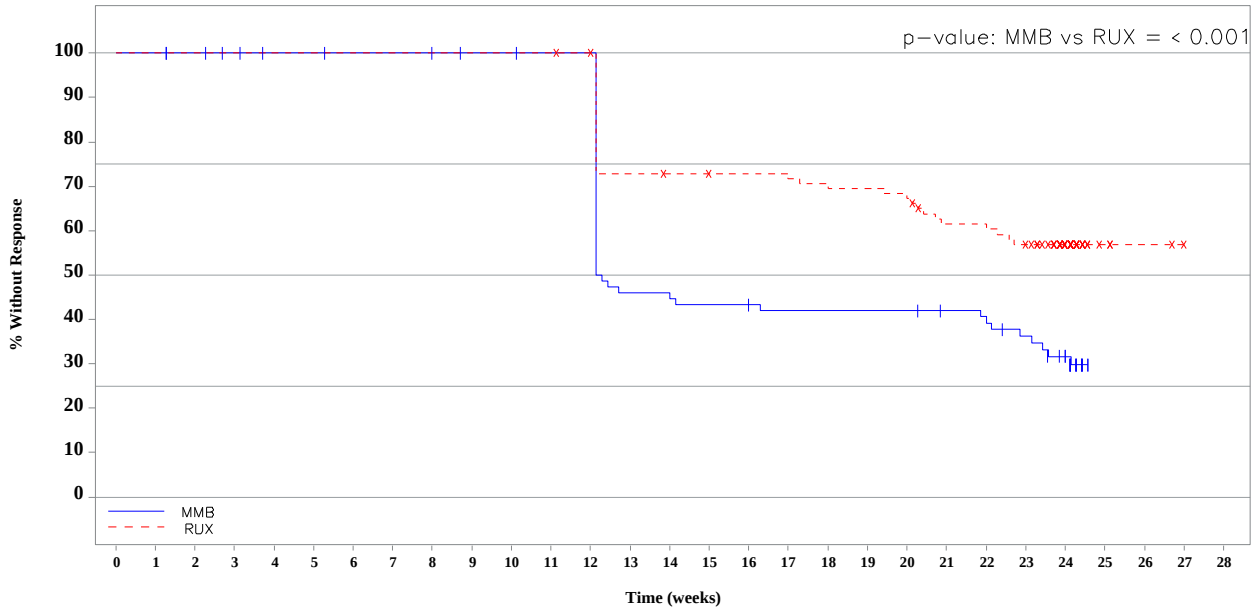
N at Risk (Events)

MMB	39 (0)	39 (0)	38 (0)	37 (0)	37 (0)	37 (0)	37 (0)	37 (0)	37 (0)	36 (0)	36 (0)	35 (0)	35 (0)	20 (15)	20 (15)	19 (16)	19 (16)	18 (16)	18 (16)	18 (16)	18 (16)	16 (16)	15 (17)	13 (18)	10 (21)	0 (21)	0 (21)	0 (21)	0 (21)
RUX	51 (0)	51 (0)	51 (0)	51 (0)	51 (0)	51 (0)	51 (0)	51 (0)	51 (0)	51 (0)	51 (0)	51 (0)	50 (0)	33 (16)	33 (16)	33 (16)	32 (16)	32 (17)	30 (19)	29 (19)	29 (20)	24 (23)	24 (24)	20 (27)	15 (27)	0 (27)	0 (27)	0 (27)	0 (27)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,na) and baseline platelet count (<100,100-200,>200 10^9/L).

Data Extracted: CRF data: 01JUL2019
Source: g-tte-any-tfr-sub.sas V.03.05 Output file: g-tte-any-tfr-svb.pdf 29AUG2023:15:20

Figure 2.2601: Kaplan-Meier Plot of Time to Any Type Transfusion Free Response
Double-blind Phase
ITT-Anemic Analysis Set



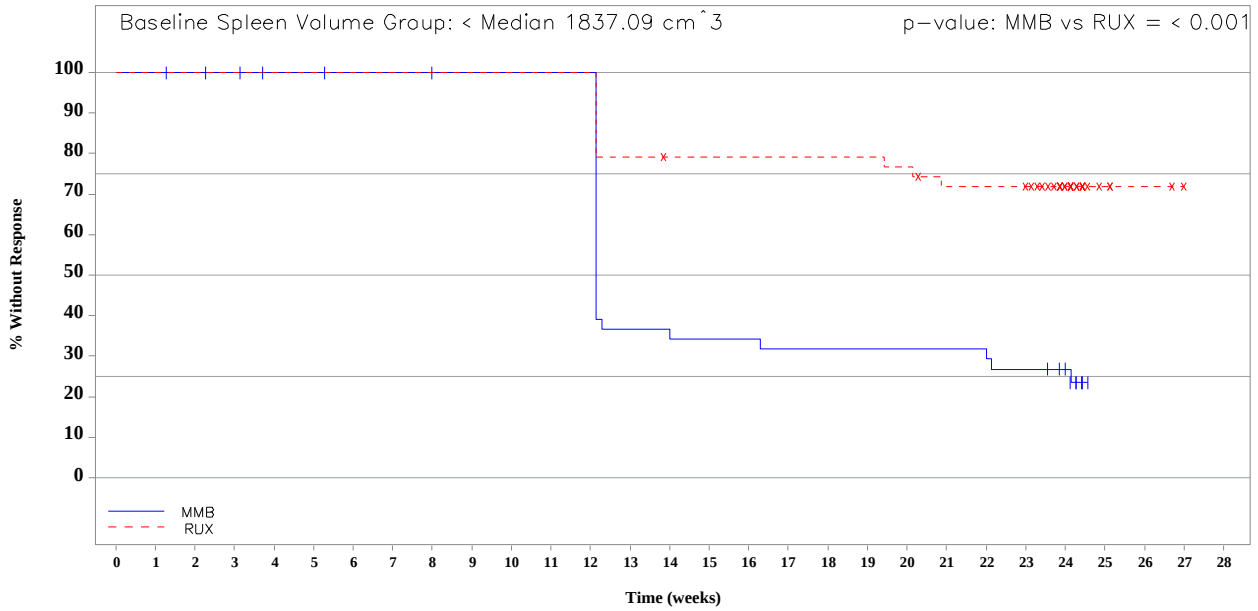
N at Risk (Events)

MMB	86 (0)	86 (0)	84 (0)	82 (0)	80 (0)	80 (0)	79 (0)	79 (0)	79 (0)	77 (0)	77 (0)	76 (0)	76 (0)	35 (41)	35 (42)	33 (43)	33 (43)	31 (44)	31 (44)	31 (44)	31 (44)	29 (44)	28 (46)	24 (48)	19 (51)	0 (52)	0 (52)	0 (52)	0 (52)
RUX	94 (0)	94 (0)	94 (0)	94 (0)	94 (0)	94 (0)	94 (0)	94 (0)	94 (0)	94 (0)	94 (0)	94 (0)	93 (0)	67 (25)	66 (25)	66 (25)	65 (25)	65 (26)	63 (28)	62 (28)	61 (30)	53 (35)	53 (36)	49 (39)	34 (39)	4 (39)	2 (39)	1 (39)	0 (39)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L).

Data Extracted: CRF data: 01JUL2019
Source: g-tte-any-tfr.sas V.03.05 Output file: g-tte-any-tfr.pdf 29AUG2023:15:20

Figure 2.1710: Kaplan-Meier Plot of Time to RBC Transfusion Free Response by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set



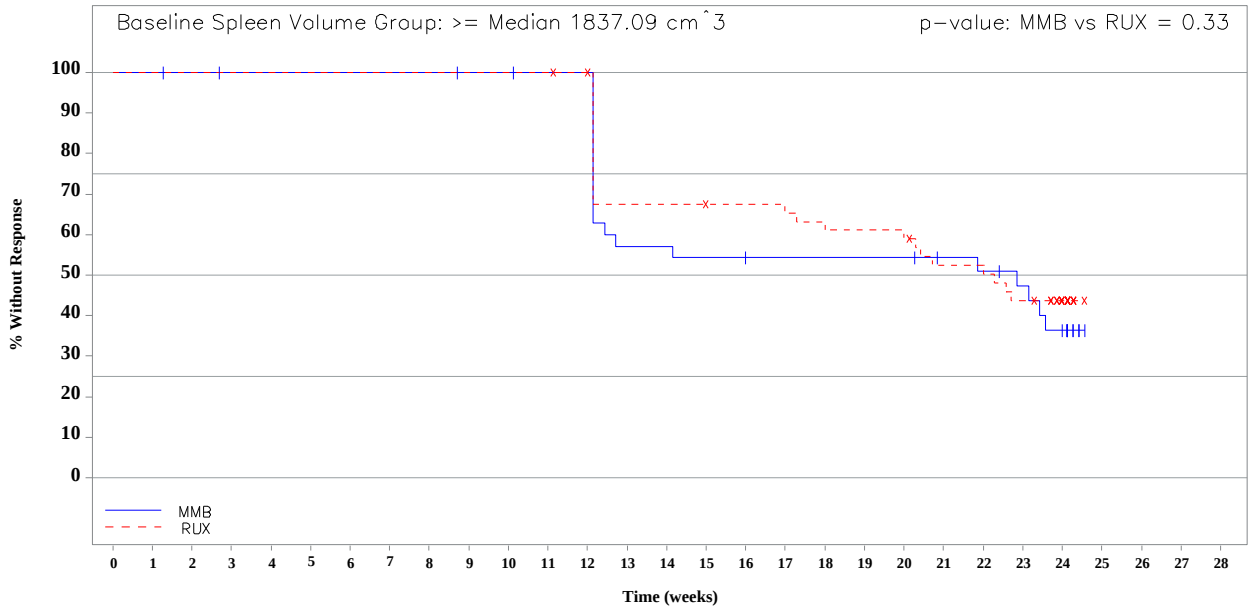
N at Risk (Events)

MMB	47 (0)	47 (0)	46 (0)	45 (0)	43 (0)	43 (0)	42 (0)	42 (0)	42 (0)	41 (0)	41 (0)	41 (0)	41 (0)	15 (26)	15 (27)	14 (27)	14 (27)	13 (28)	13 (28)	13 (28)	13 (28)	13 (28)	13 (29)	11 (30)	9 (30)	0 (31)	0 (31)	0 (31)	0 (31)
RUX	43 (0)	43 (0)	43 (0)	43 (0)	43 (0)	43 (0)	43 (0)	43 (0)	43 (0)	43 (0)	43 (0)	43 (0)	43 (0)	34 (9)	33 (9)	33 (9)	33 (9)	33 (9)	33 (9)	33 (9)	33 (9)	32 (10)	29 (12)	29 (12)	29 (12)	19 (12)	4 (12)	2 (12)	1 (12)	0 (12)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L).

Data Extracted: CRF data: 01JUL2019
Source: g-tte-tfr-sub.sas V.03.05 Output file: g-tte-tfr-svb.pdf 29AUG2023:15:19

Figure 2.1710: Kaplan-Meier Plot of Time to RBC Transfusion Free Response by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set



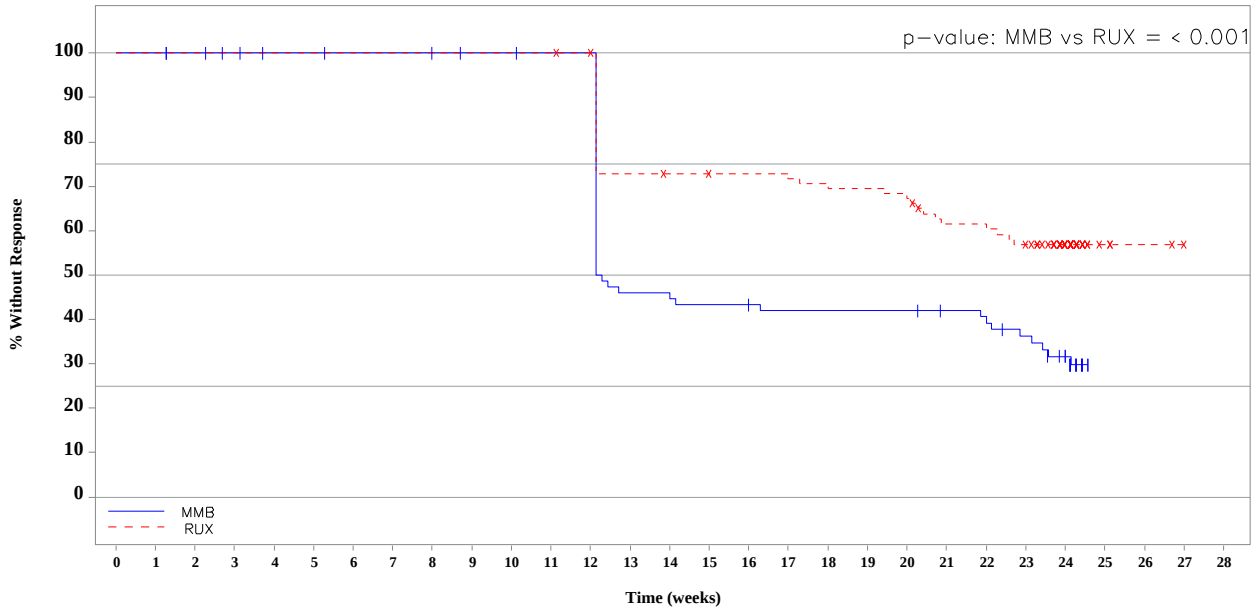
N at Risk (Events)

MMB	39 (0)	39 (0)	38 (0)	37 (0)	37 (0)	37 (0)	37 (0)	37 (0)	37 (0)	36 (0)	36 (0)	35 (0)	35 (0)	20 (15)	20 (15)	19 (16)	19 (16)	18 (16)	18 (16)	18 (16)	18 (16)	16 (16)	15 (17)	13 (18)	10 (21)	0 (21)	0 (21)	0 (21)	0 (21)
RUX	51 (0)	51 (0)	51 (0)	51 (0)	51 (0)	51 (0)	51 (0)	51 (0)	51 (0)	51 (0)	51 (0)	51 (0)	50 (0)	33 (16)	33 (16)	33 (16)	32 (16)	32 (17)	30 (19)	29 (19)	29 (20)	24 (23)	24 (24)	20 (27)	15 (27)	0 (27)	0 (27)	0 (27)	0 (27)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,na) and baseline platelet count (<100,100-200,>200 10^9/L).

Data Extracted: CRF data: 01JUL2019
Source: g-tte-tfr-sub.sas V.03.05 Output file: g-tte-tfr-svb.pdf 29AUG2023:15:19

Figure 2.1701: Kaplan-Meier Plot of Time to RBC Transfusion Free Response
Double-blind Phase
ITT-Anemic Analysis Set



N at Risk (Events)

MMB	86 (0)	86 (0)	84 (0)	82 (0)	80 (0)	80 (0)	79 (0)	79 (0)	79 (0)	77 (0)	77 (0)	76 (0)	76 (0)	35 (41)	35 (42)	33 (43)	33 (43)	31 (44)	31 (44)	31 (44)	31 (44)	29 (44)	28 (46)	24 (48)	19 (51)	0 (52)	0 (52)	0 (52)	0 (52)
RUX	94 (0)	94 (0)	94 (0)	94 (0)	94 (0)	94 (0)	94 (0)	94 (0)	94 (0)	94 (0)	94 (0)	94 (0)	93 (0)	67 (25)	66 (25)	66 (25)	65 (25)	65 (26)	63 (28)	62 (28)	61 (30)	53 (35)	53 (36)	49 (39)	34 (39)	4 (39)	2 (39)	1 (39)	0 (39)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L).

Data Extracted: CRF data: 01JUL2019
Source: g-tte-tfr.sas V.03.05 Output file: g-tte-tfr.pdf 29AUG2023:15:19

GSK Oncology

Study GS-US-352-0101

Table 2.4601: Analysis of Rate of Any Type Transfusion Free Response at Week 24 and at Week 12

Double-blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Any Type Transfusion Free Rate at Week 24			
Responder, n(%)	31 (36.0%)	19 (20.2%)	50 (27.8%)
95% Exact CI	0.2597, 0.4712	0.1263, 0.2975	0.2137, 0.3493
Proportion Difference - Stratified CMH Method (95% CI)	0.19 (0.06, 0.32)		
p-value	0.004		
Proportion Difference - Unstratified CMH Method (95% CI)	0.16 (0.03, 0.29)		
p-value	0.018		
Proportion Difference - Unstratified Exact Method (95% CI)	0.16 (0.01, 0.30)		
p-value	0.020		
Unadjusted Inverse Relative Risk (95% CI)	0.56 (0.34, 0.92)		
p-value [1]	0.021		
Unadjusted Inverse Odds Ratio (95% CI)	0.45 (0.23, 0.88)		
p-value [1]	0.019		
Unadjusted Absolute Risk Difference (95% CI)	0.16 (0.03, 0.29)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.50 (0.32, 0.80)		
p-value [2]	0.004		
Non-responder, n(%)	55 (64.0%)	75 (79.8%)	130 (72.2%)
Any Type Transfusion within 12 weeks prior to Week 24	39 (45.3%)	67 (71.3%)	106 (58.9%)
Discontinued prior to week 24	16 (18.6%)	8 (8.5%)	24 (13.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes,no), and baseline platelet count (<100,100-200,>200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

GSK Oncology

Study GS-US-352-0101

Table 2.4601: Analysis of Rate of Any Type Transfusion Free Response at Week 24 and at Week 12

Double-blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Any Type Transfusion Free Rate at Week 12			
Responder, n(%)	37 (43.0%)	25 (26.6%)	62 (34.4%)
95% Exact CI	0.3239, 0.5415	0.1801, 0.3671	0.2753, 0.4188
Proportion Difference - Stratified CMH Method (95% CI)		0.20 (0.07, 0.33)	
p-value		0.002	
Proportion Difference - Unstratified CMH Method (95% CI)		0.16 (0.03, 0.30)	
p-value		0.020	
Proportion Difference - Unstratified Exact Method (95% CI)		0.16 (0.02, 0.30)	
p-value		0.028	
Unadjusted Inverse Relative Risk (95% CI)		0.62 (0.41, 0.94)	
p-value [1]		0.023	
Unadjusted Inverse Odds Ratio (95% CI)		0.48 (0.26, 0.90)	
p-value [1]		0.021	
Unadjusted Absolute Risk Difference (95% CI)		0.16 (0.03, 0.30)	
Adjusted Inverse Relative Risk (95% CI) [2]		0.55 (0.38, 0.82)	
p-value [2]		0.003	
Non-responder, n(%)	49 (57.0%)	69 (73.4%)	118 (65.6%)
Any Type Transfusion within 12 weeks prior to Week 12	39 (45.3%)	69 (73.4%)	108 (60.0%)
Discontinued prior to week 12	10 (11.6%)	0	10 (5.6%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes,no), and baseline platelet count (<100,100-200,>200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

GSK Oncology

Study GS-US-352-0101

Table 2.4101: Analysis of Rate of Any Type Transfusion Free Response by Week 24

Double-blind Phase

ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Any Type Transfusion Free Rate by Week 24 in DB Phase			
Responder, n(%)	42 (48.8%)	55 (58.5%)	97 (53.9%)
Unadjusted Inverse Relative Risk (95% CI)	1.20 (0.91, 1.58)		
p-value [1]	0.20		
Unadjusted Inverse Odds Ratio (95% CI)	1.48 (0.82, 2.66)		
p-value [1]	0.19		
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.24, 0.05)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.08 (0.86, 1.36)		
p-value [2]	0.53		
Subjects not Transfusion Free at Baseline, n	56	44	100
New Any Type Transfusion Free Rate by Week 24			
Responder, n/N(%)	12/56 (21.4%)	5/44 (11.4%)	17/100 (17.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

Source: t-atf-by24-db-gba.sas V.03.05 Output file: t-atf-by24-db-gba.pdf 29AUG2023: 8:56

GSK Oncology
Study GS-US-352-0101

Table 2.4402: Analysis of Duration of Any Type Transfusion Free Response by Age
Double-blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Subjects with Event					
Loss of Any Type Transfusion Free Response, n(%)	4 (16.7%)	2 (5.6%)	3 (4.8%)	5 (8.6%)	
Censor					
Subjects Censored, n(%)	20 (83.3%)	34 (94.4%)	59 (95.2%)	53 (91.4%)	
Non-Responder: Censored at Randomization Date	6 (30.0%)	17 (50.0%)	28 (47.5%)	38 (71.7%)	
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	14 (70.0%)	17 (50.0%)	31 (52.5%)	15 (28.3%)	
Kaplan-Meier Estimate of Duration of Any Type Transfusion Free Response (Weeks)					
25-percentile (95% CI)	12.14 (0.29, NE)	NE (2.29, NE)	NE (12.14, NE)	4.43 (1.29, NE)	
Median (95% CI)	NE (12.14, NE)	NE (NE, NE)	NE (NE, NE)	NE (4.43, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 12.43	0.14, 12.57	0.14, 12.71	0.14, 13.14	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusions of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-any-tfr-sub.sas V.03.05 Output file: t-dur-any-tfr-age.pdf 24AUG2023:12:45

GSK Oncology
Study GS-US-352-0101

Table 2.4404: Analysis of Duration of Any Type Transfusion Free Response by Region
Double-blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Subjects with Event					
Loss of Any Type Transfusion Free Response, n(%)	6 (11.3%)	3 (5.9%)	1 (3.0%)	4 (9.3%)	
Censor					
Subjects Censored, n(%)	47 (88.7%)	48 (94.1%)	32 (97.0%)	39 (90.7%)	
Non-Responder: Censored at Randomization Date	25 (53.2%)	33 (68.8%)	9 (28.1%)	22 (56.4%)	
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	22 (46.8%)	15 (31.3%)	23 (71.9%)	17 (43.6%)	
Kaplan-Meier Estimate of Duration of Any Type Transfusion Free Response (Weeks)					
25-percentile (95% CI)	12.14 (0.29, NE)	NE (2.14, NE)	NE (0.57, NE)	NE (1.29, NE)	
Median (95% CI)	NE (12.14, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 12.57	0.14, 12.57	0.14, 12.71	0.14, 13.14	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusions of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment. P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-any-tfr-sub.sas V.03.05 Output file: t-dur-any-tfr-geo.pdf 24AUG2023:12:45

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Table 2.4407: Analysis of Duration of Any Type Transfusion Free Response by Baseline Hemoglobin Level
Double-blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Subjects with Event					
Loss of Any Type Transfusion Free Response, n(%)	1 (3.6%)	1 (4.8%)	6 (10.3%)	6 (8.2%)	
Censor					
Subjects Censored, n(%)	27 (96.4%)	20 (95.2%)	52 (89.7%)	67 (91.8%)	
Non-Responder: Censored at Randomization Date	16 (59.3%)	16 (80.0%)	18 (34.6%)	39 (58.2%)	
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	11 (40.7%)	4 (20.0%)	34 (65.4%)	28 (41.8%)	
Kaplan-Meier Estimate of Duration of Any Type Transfusion Free Response (Weeks)					
25-percentile (95% CI)	NE (5.29, NE)	NE (3.86, NE)	NE (10.71, NE)	NE (2.29, NE)	
Median (95% CI)	NE (5.29, NE)	NE (3.86, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (3.86, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 12.57	0.14, 12.14	0.14, 12.71	0.14, 13.14	
Stratified Log-Rank Test p-value	0.046		0.30		
Adjusted Hazard Ratio (95% CI)	<0.01 (<0.01, NE)		0.79 (0.25, 2.52)		
Unstratified Log-Rank Test p-value	0.54		0.75		
Unadjusted Hazard Ratio (95% CI)	0.43 (0.03, 7.04)		0.84 (0.27, 2.61)		
P-value for interaction test					0.29

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusions of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-any-tfr-sub.sas V.03.05 Output file: t-dur-any-tfr-hgb.pdf 24AUG2023:12:45

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Table 2.4406: Analysis of Duration of Any Type Transfusion Free Response by Baseline IPSS Two-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Subjects with Event					
Loss of Any Type Transfusion Free Response, n(%)	3 (10.7%)	0	4 (6.9%)	7 (10.0%)	
Censor					
Subjects Censored, n(%)	25 (89.3%)	24 (100.0%)	54 (93.1%)	63 (90.0%)	
Non-Responder: Censored at Randomization Date	9 (36.0%)	14 (58.3%)	25 (46.3%)	41 (65.1%)	
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	16 (64.0%)	10 (41.7%)	29 (53.7%)	22 (34.9%)	
Kaplan-Meier Estimate of Duration of Any Type Transfusion Free Response (Weeks)					
25-percentile (95% CI)	NE (0.29, NE)	NE (NE, NE)	NE (5.29, NE)	4.43 (2.29, NE)	
Median (95% CI)	NE (12.14, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 12.43	0.14, 12.57	0.14, 12.71	0.14, 13.14	
Stratified Log-Rank Test p-value	NE		0.098		
Adjusted Hazard Ratio (95% CI)	1.00 (0.00, NE)		0.36 (0.10, 1.33)		
Unstratified Log-Rank Test p-value	0.19		0.26		
Unadjusted Hazard Ratio (95% CI)	>999.99 (0.00, NE)		0.50 (0.14, 1.70)		
P-value for interaction test					1.00

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusions of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-any-tfr-sub.sas V.03.05 Output file: t-dur-any-tfr-ipss2.pdf 24AUG2023:12:45

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Table 2.4405: Analysis of Duration of Any Type Transfusion Free Response by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Subjects with Event				
Loss of Any Type Transfusion Free Response, n(%)	0	0	3 (11.5%)	0
Censor				
Subjects Censored, n(%)	2 (100.0%)	4 (100.0%)	23 (88.5%)	20 (100.0%)
Non-Responder: Censored at Randomization Date	0	2 (50.0%)	9 (39.1%)	12 (60.0%)
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	2 (100.0%)	2 (50.0%)	14 (60.9%)	8 (40.0%)
Kaplan-Meier Estimate of Duration of Any Type Transfusion Free Response (Weeks)				
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (0.29, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (12.14, NE)	NE (NE, NE)
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Min, Max	11.71, 12.14	0.14, 12.43	0.14, 12.43	0.14, 12.57
Stratified Log-Rank Test p-value	NA		NA	
Adjusted Hazard Ratio (95% CI)	NA		NA	
Unstratified Log-Rank Test p-value	NA		NA	
Unadjusted Hazard Ratio (95% CI)	NA		NA	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusions of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-any-tfr-sub.sas V.03.05 Output file: t-dur-any-tfr-ipss3.pdf 24AUG2023:12:45

Table 2.4405: Analysis of Duration of Any Type Transfusion Free Response by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=58)	High Risk RUX (N=70)	p-value
Subjects with Event			
Loss of Any Type Transfusion Free Response, n(%)	4 (6.9%)	7 (10.0%)	
Censor			
Subjects Censored, n(%)	54 (93.1%)	63 (90.0%)	
Non-Responder: Censored at Randomization Date	25 (46.3%)	41 (65.1%)	
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	29 (53.7%)	22 (34.9%)	
Kaplan-Meier Estimate of Duration of Any Type Transfusion Free Response (Weeks)			
25-percentile (95% CI)	NE (5.29, NE)	4.43 (2.29, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 12.71	0.14, 13.14	
Stratified Log-Rank Test p-value	NA		
Adjusted Hazard Ratio (95% CI)	NA		
Unstratified Log-Rank Test p-value	NA		
Unadjusted Hazard Ratio (95% CI)	NA		
P-value for interaction test			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusions of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-any-tfr-sub.sas V.03.05 Output file: t-dur-any-tfr-ipss3.pdf 24AUG2023:12:45

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Table 2.4408: Analysis of Duration of Any Type Transfusion Free Response by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=16)	RUX (N=28)	MMB (N=11)	RUX (N=12)
Subjects with Event				
Loss of Any Type Transfusion Free Response, n(%)	4 (25.0%)	3 (10.7%)	0	1 (8.3%)
Censor				
Subjects Censored, n(%)	12 (75.0%)	25 (89.3%)	11 (100.0%)	11 (91.7%)
Non-Responder: Censored at Randomization Date	8 (66.7%)	18 (72.0%)	5 (45.5%)	10 (90.9%)
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	4 (33.3%)	7 (28.0%)	6 (54.5%)	1 (9.1%)
Kaplan-Meier Estimate of Duration of Any Type Transfusion Free Response (Weeks)				
25-percentile (95% CI)	5.64 (0.29, NE)	4.43 (1.29, NE)	NE (NE, NE)	2.29 (2.29, NE)
Median (95% CI)	12.14 (0.29, NE)	NE (1.29, NE)	NE (NE, NE)	NE (2.29, NE)
75-percentile (95% CI)	NE (10.71, NE)	NE (NE, NE)	NE (NE, NE)	NE (2.29, NE)
Min, Max	0.14, 12.71	0.14, 12.71	0.14, 12.57	0.14, 12.57
Stratified Log-Rank Test p-value	NA		NA	
Adjusted Hazard Ratio (95% CI)	NA		NA	
Unstratified Log-Rank Test p-value	NA		NA	
Unadjusted Hazard Ratio (95% CI)	NA		NA	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusions of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment. P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-any-tfr-sub.sas V.03.05 Output file: t-dur-any-tfr-mf.pdf 24AUG2023:12:45

Table 2.4408: Analysis of Duration of Any Type Transfusion Free Response by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	Primary Myelofibrosis MMB (N=59)	Primary Myelofibrosis RUX (N=54)	p-value
Subjects with Event			
Loss of Any Type Transfusion Free Response, n(%)	3 (5.1%)	3 (5.6%)	
Censor			
Subjects Censored, n(%)	56 (94.9%)	51 (94.4%)	
Non-Responder: Censored at Randomization Date	21 (37.5%)	27 (52.9%)	
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	35 (62.5%)	24 (47.1%)	
Kaplan-Meier Estimate of Duration of Any Type Transfusion Free Response (Weeks)			
25-percentile (95% CI)	NE (12.14, NE)	NE (2.29, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 12.43	0.14, 13.14	
Stratified Log-Rank Test p-value	NA		
Adjusted Hazard Ratio (95% CI)	NA		
Unstratified Log-Rank Test p-value	NA		
Unadjusted Hazard Ratio (95% CI)	NA		
P-value for interaction test			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusions of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-any-tfr-sub.sas V.03.05 Output file: t-dur-any-tfr-mf.pdf 24AUG2023:12:45

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Table 2.4403: Analysis of Duration of Any Type Transfusion Free Response by Gender
Double-blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Subjects with Event					
Loss of Any Type Transfusion Free Response, n(%)	5 (10.0%)	4 (7.1%)	2 (5.6%)	3 (7.9%)	
Censor					
Subjects Censored, n(%)	45 (90.0%)	52 (92.9%)	34 (94.4%)	35 (92.1%)	
Non-Responder: Censored at Randomization Date	22 (48.9%)	34 (65.4%)	12 (35.3%)	21 (60.0%)	
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	23 (51.1%)	18 (34.6%)	22 (64.7%)	14 (40.0%)	
Kaplan-Meier Estimate of Duration of Any Type Transfusion Free Response (Weeks)					
25-percentile (95% CI)	NE (0.29, NE)	NE (2.14, NE)	NE (10.71, NE)	NE (1.29, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 12.71	0.14, 13.14	0.14, 12.29	0.14, 12.71	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusions of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-any-tfr-sub.sas V.03.05 Output file: t-dur-any-tfr-sex.pdf 24AUG2023:12:45

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Table 2.4410: Analysis of Duration of Any Type Transfusion Free Response by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Subjects with Event					
Loss of Any Type Transfusion Free Response, n(%)	4 (8.5%)	1 (2.3%)	3 (7.7%)	6 (11.8%)	
Censor					
Subjects Censored, n(%)	43 (91.5%)	42 (97.7%)	36 (92.3%)	45 (88.2%)	
Non-Responder: Censored at Randomization Date	16 (37.2%)	31 (73.8%)	18 (50.0%)	24 (53.3%)	
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	27 (62.8%)	11 (26.2%)	18 (50.0%)	21 (46.7%)	
Kaplan-Meier Estimate of Duration of Any Type Transfusion Free Response (Weeks)					
25-percentile (95% CI)	NE (5.29, NE)	NE (1.29, NE)	NE (0.29, NE)	4.43 (2.29, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (12.14, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 12.71	0.14, 13.14	0.14, 12.57	0.14, 12.57	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusions of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-any-tfr-sub.sas V.03.05 Output file: t-dur-any-tfr-svb.pdf 24AUG2023:12:45

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Table 2.4409: Analysis of Duration of Any Type Transfusion Free Response by Baseline TSS
Double-blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Subjects with Event					
Loss of Any Type Transfusion Free Response, n(%)	4 (9.1%)	4 (7.3%)	3 (7.3%)	3 (7.9%)	
Censor					
Subjects Censored, n(%)	40 (90.9%)	51 (92.7%)	38 (92.7%)	35 (92.1%)	
Non-Responder: Censored at Randomization Date	15 (37.5%)	31 (60.8%)	19 (50.0%)	23 (65.7%)	
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	25 (62.5%)	20 (39.2%)	19 (50.0%)	12 (34.3%)	
Kaplan-Meier Estimate of Duration of Any Type Transfusion Free Response (Weeks)					
25-percentile (95% CI)	NE (5.29, NE)	NE (1.29, NE)	NE (0.29, NE)	NE (2.29, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (4.43, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 12.43	0.14, 13.14	0.14, 12.71	0.14, 12.71	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusions of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-any-tfr-sub.sas V.03.05 Output file: t-dur-any-tfr-tss.pdf 24AUG2023:12:45

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Table 2.4401: Analysis of Duration of Any Type Transfusion Free Response
Double-blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Subjects with Event		
Loss of Any Type Transfusion Free Response, n(%)	7 (8.1%)	7 (7.4%)
Censor		
Subjects Censored, n(%)	79 (91.9%)	87 (92.6%)
Non-Responder: Censored at Randomization Date	34 (43.0%)	55 (63.2%)
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	45 (57.0%)	32 (36.8%)
Kaplan-Meier Estimate of Duration of Any Type Transfusion Free Response (Weeks)		
25-percentile (95% CI)	NE (12.14, NE)	NE (2.29, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)
Min, Max	0.14, 12.71	0.14, 13.14
Stratified Log-Rank Test p-value	0.16	
Adjusted Hazard Ratio (95% CI)	0.59 (0.20, 1.75)	
Unstratified Log-Rank Test p-value	0.56	
Unadjusted Hazard Ratio (95% CI)	0.74 (0.26, 2.11)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusions of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-any-tfr.sas V.03.05 Output file: t-dur-any-tfr.pdf 24AUG2023:12:44

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Table 2.2602: Analysis of Duration of RBC Transfusion Free Response by Age
Double-blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Subjects with Event					
Loss of RBC Transfusion Free Response, n(%)	3 (12.5%)	2 (5.6%)	3 (4.8%)	5 (8.6%)	
Censor					
Subjects Censored, n(%)	21 (87.5%)	34 (94.4%)	59 (95.2%)	53 (91.4%)	
Non-Responder: Censored at Randomization Date	6 (28.6%)	17 (50.0%)	28 (47.5%)	38 (71.7%)	
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	15 (71.4%)	17 (50.0%)	31 (52.5%)	15 (28.3%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Free Response (Weeks)					
25-percentile (95% CI)	NE (0.29, NE)	NE (2.29, NE)	NE (12.14, NE)	4.43 (1.29, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (4.43, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 12.43	0.14, 12.57	0.14, 12.71	0.14, 13.14	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-rbc-tfr-sub.sas V.03.05 Output file: t-dur-rbc-tfr-age.pdf 24AUG2023:11:02

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Table 2.2604: Analysis of Duration of RBC Transfusion Free Response by Region
Double-blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Subjects with Event					
Loss of RBC Transfusion Free Response, n(%)	5 (9.4%)	3 (5.9%)	1 (3.0%)	4 (9.3%)	
Censor					
Subjects Censored, n(%)	48 (90.6%)	48 (94.1%)	32 (97.0%)	39 (90.7%)	
Non-Responder: Censored at Randomization Date	25 (52.1%)	33 (68.8%)	9 (28.1%)	22 (56.4%)	
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	23 (47.9%)	15 (31.3%)	23 (71.9%)	17 (43.6%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Free Response (Weeks)					
25-percentile (95% CI)	NE (0.29, NE)	NE (2.14, NE)	NE (0.57, NE)	NE (1.29, NE)	
Median (95% CI)	NE (12.14, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 12.57	0.14, 12.57	0.14, 12.71	0.14, 13.14	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-rbc-tfr-sub.sas V.03.05 Output file: t-dur-rbc-tfr-geo.pdf 24AUG2023:11:02

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Table 2.2607: Analysis of Duration of RBC Transfusion Free Response by Baseline Hemoglobin Level
Double-blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Subjects with Event					
Loss of RBC Transfusion Free Response, n(%)	1 (3.6%)	1 (4.8%)	5 (8.6%)	6 (8.2%)	
Censor					
Subjects Censored, n(%)	27 (96.4%)	20 (95.2%)	53 (91.4%)	67 (91.8%)	
Non-Responder: Censored at Randomization Date	16 (59.3%)	16 (80.0%)	18 (34.0%)	39 (58.2%)	
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	11 (40.7%)	4 (20.0%)	35 (66.0%)	28 (41.8%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Free Response (Weeks)					
25-percentile (95% CI)	NE (5.29, NE)	NE (3.86, NE)	NE (10.71, NE)	NE (2.29, NE)	
Median (95% CI)	NE (5.29, NE)	NE (3.86, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (3.86, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 12.57	0.14, 12.14	0.14, 12.71	0.14, 13.14	
Stratified Log-Rank Test p-value	0.046		0.30		
Adjusted Hazard Ratio (95% CI)	<0.01 (<0.01, NE)		0.65 (0.19, 2.22)		
Unstratified Log-Rank Test p-value	0.54		0.55		
Unadjusted Hazard Ratio (95% CI)	0.43 (0.03, 7.04)		0.70 (0.21, 2.29)		
P-value for interaction test					0.37

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-rbc-tfr-sub.sas V.03.05 Output file: t-dur-rbc-tfr-hgb.pdf 24AUG2023:11:03

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Table 2.2606: Analysis of Duration of RBC Transfusion Free Response by Baseline IPSS Two-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Subjects with Event					
Loss of RBC Transfusion Free Response, n(%)	2 (7.1%)	0	4 (6.9%)	7 (10.0%)	
Censor					
Subjects Censored, n(%)	26 (92.9%)	24 (100.0%)	54 (93.1%)	63 (90.0%)	
Non-Responder: Censored at Randomization Date	9 (34.6%)	14 (58.3%)	25 (46.3%)	41 (65.1%)	
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	17 (65.4%)	10 (41.7%)	29 (53.7%)	22 (34.9%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Free Response (Weeks)					
25-percentile (95% CI)	NE (0.29, NE)	NE (NE, NE)	NE (5.29, NE)	4.43 (2.29, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 12.43	0.14, 12.57	0.14, 12.71	0.14, 13.14	
Stratified Log-Rank Test p-value	NE		0.098		
Adjusted Hazard Ratio (95% CI)	1.00 (0.00, NE)		0.36 (0.10, 1.33)		
Unstratified Log-Rank Test p-value	0.30		0.26		
Unadjusted Hazard Ratio (95% CI)	>999.99 (0.00, NE)		0.50 (0.14, 1.70)		
P-value for interaction test					1.00

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-rbc-tfr-sub.sas V.03.05 Output file: t-dur-rbc-tfr-ipss2.pdf 24AUG2023:11:03

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Table 2.2605: Analysis of Duration of RBC Transfusion Free Response by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Subjects with Event				
Loss of RBC Transfusion Free Response, n(%)	0	0	2 (7.7%)	0
Censor				
Subjects Censored, n(%)	2 (100.0%)	4 (100.0%)	24 (92.3%)	20 (100.0%)
Non-Responder: Censored at Randomization Date	0	2 (50.0%)	9 (37.5%)	12 (60.0%)
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	2 (100.0%)	2 (50.0%)	15 (62.5%)	8 (40.0%)
Kaplan-Meier Estimate of Duration of RBC Transfusion Free Response (Weeks)				
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (0.29, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Min, Max	11.71, 12.14	0.14, 12.43	0.14, 12.43	0.14, 12.57
Stratified Log-Rank Test p-value	NA		NA	
Adjusted Hazard Ratio (95% CI)	NA		NA	
Unstratified Log-Rank Test p-value	NA		NA	
Unadjusted Hazard Ratio (95% CI)	NA		NA	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-rbc-tfr-sub.sas V.03.05 Output file: t-dur-rbc-tfr-ipss3.pdf 24AUG2023:11:03

Table 2.2605: Analysis of Duration of RBC Transfusion Free Response by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=58)	High Risk RUX (N=70)	p-value
Subjects with Event			
Loss of RBC Transfusion Free Response, n(%)	4 (6.9%)	7 (10.0%)	
Censor			
Subjects Censored, n(%)	54 (93.1%)	63 (90.0%)	
Non-Responder: Censored at Randomization Date	25 (46.3%)	41 (65.1%)	
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	29 (53.7%)	22 (34.9%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Free Response (Weeks)			
25-percentile (95% CI)	NE (5.29, NE)	4.43 (2.29, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 12.71	0.14, 13.14	
Stratified Log-Rank Test p-value	NA		
Adjusted Hazard Ratio (95% CI)	NA		
Unstratified Log-Rank Test p-value	NA		
Unadjusted Hazard Ratio (95% CI)	NA		
P-value for interaction test			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-rbc-tfr-sub.sas V.03.05 Output file: t-dur-rbc-tfr-ipss3.pdf 24AUG2023:11:03

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Table 2.2608: Analysis of Duration of RBC Transfusion Free Response by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=16)	RUX (N=28)	MMB (N=11)	RUX (N=12)
Subjects with Event				
Loss of RBC Transfusion Free Response, n(%)	3 (18.8%)	3 (10.7%)	0	1 (8.3%)
Censor				
Subjects Censored, n(%)	13 (81.3%)	25 (89.3%)	11 (100.0%)	11 (91.7%)
Non-Responder: Censored at Randomization Date	8 (61.5%)	18 (72.0%)	5 (45.5%)	10 (90.9%)
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	5 (38.5%)	7 (28.0%)	6 (54.5%)	1 (9.1%)
Kaplan-Meier Estimate of Duration of RBC Transfusion Free Response (Weeks)				
25-percentile (95% CI)	5.64 (0.29, NE)	4.43 (1.29, NE)	NE (NE, NE)	2.29 (2.29, NE)
Median (95% CI)	NE (0.29, NE)	NE (1.29, NE)	NE (NE, NE)	NE (2.29, NE)
75-percentile (95% CI)	NE (10.71, NE)	NE (NE, NE)	NE (NE, NE)	NE (2.29, NE)
Min, Max	0.14, 12.71	0.14, 12.71	0.14, 12.57	0.14, 12.57
Stratified Log-Rank Test p-value	NA		NA	
Adjusted Hazard Ratio (95% CI)	NA		NA	
Unstratified Log-Rank Test p-value	NA		NA	
Unadjusted Hazard Ratio (95% CI)	NA		NA	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment. P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-rbc-tfr-sub.sas V.03.05 Output file: t-dur-rbc-tfr-mf.pdf 24AUG2023:11:03

Table 2.2608: Analysis of Duration of RBC Transfusion Free Response by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	Primary Myelofibrosis MMB (N=59)	Primary Myelofibrosis RUX (N=54)	p-value
Subjects with Event			
Loss of RBC Transfusion Free Response, n(%)	3 (5.1%)	3 (5.6%)	
Censor			
Subjects Censored, n(%)	56 (94.9%)	51 (94.4%)	
Non-Responder: Censored at Randomization Date	21 (37.5%)	27 (52.9%)	
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	35 (62.5%)	24 (47.1%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Free Response (Weeks)			
25-percentile (95% CI)	NE (12.14, NE)	NE (2.29, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 12.43	0.14, 13.14	
Stratified Log-Rank Test p-value	NA		
Adjusted Hazard Ratio (95% CI)	NA		
Unstratified Log-Rank Test p-value	NA		
Unadjusted Hazard Ratio (95% CI)	NA		
P-value for interaction test			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment. P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-rbc-tfr-sub.sas V.03.05 Output file: t-dur-rbc-tfr-mf.pdf 24AUG2023:11:03

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Table 2.2603: Analysis of Duration of RBC Transfusion Free Response by Gender
Double-blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Subjects with Event					
Loss of RBC Transfusion Free Response, n(%)	5 (10.0%)	4 (7.1%)	1 (2.8%)	3 (7.9%)	
Censor					
Subjects Censored, n(%)	45 (90.0%)	52 (92.9%)	35 (97.2%)	35 (92.1%)	
Non-Responder: Censored at Randomization Date	22 (48.9%)	34 (65.4%)	12 (34.3%)	21 (60.0%)	
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	23 (51.1%)	18 (34.6%)	23 (65.7%)	14 (40.0%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Free Response (Weeks)					
25-percentile (95% CI)	NE (0.29, NE)	NE (2.14, NE)	NE (10.71, NE)	NE (1.29, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 12.71	0.14, 13.14	0.14, 12.29	0.14, 12.71	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-rbc-tfr-sub.sas V.03.05 Output file: t-dur-rbc-tfr-sex.pdf 24AUG2023:11:02

GSK Oncology
Study GS-US-352-0101

Table 2.2610: Analysis of Duration of RBC Transfusion Free Response by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Subjects with Event					
Loss of RBC Transfusion Free Response, n(%)	4 (8.5%)	1 (2.3%)	2 (5.1%)	6 (11.8%)	
Censor					
Subjects Censored, n(%)	43 (91.5%)	42 (97.7%)	37 (94.9%)	45 (88.2%)	
Non-Responder: Censored at Randomization Date	16 (37.2%)	31 (73.8%)	18 (48.6%)	24 (53.3%)	
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	27 (62.8%)	11 (26.2%)	19 (51.4%)	21 (46.7%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Free Response (Weeks)					
25-percentile (95% CI)	NE (5.29, NE)	NE (1.29, NE)	NE (0.29, NE)	4.43 (2.29, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 12.71	0.14, 13.14	0.14, 12.57	0.14, 12.57	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-rbc-tfr-sub.sas V.03.05 Output file: t-dur-rbc-tfr-svb.pdf 24AUG2023:11:03

GSK Oncology
Study GS-US-352-0101

Table 2.2609: Analysis of Duration of RBC Transfusion Free Response by Baseline TSS
Double-blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Subjects with Event					
Loss of RBC Transfusion Free Response, n(%)	4 (9.1%)	4 (7.3%)	2 (4.9%)	3 (7.9%)	
Censor					
Subjects Censored, n(%)	40 (90.9%)	51 (92.7%)	39 (95.1%)	35 (92.1%)	
Non-Responder: Censored at Randomization Date	15 (37.5%)	31 (60.8%)	19 (48.7%)	23 (65.7%)	
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	25 (62.5%)	20 (39.2%)	20 (51.3%)	12 (34.3%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Free Response (Weeks)					
25-percentile (95% CI)	NE (5.29, NE)	NE (1.29, NE)	NE (0.29, NE)	NE (2.29, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (4.43, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 12.43	0.14, 13.14	0.14, 12.71	0.14, 12.71	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-rbc-tfr-sub.sas V.03.05 Output file: t-dur-rbc-tfr-tss.pdf 24AUG2023:11:03

Table 2.2601: Analysis of Duration of RBC Transfusion Free Response
Double-blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Subjects with Event		
Loss of RBC Transfusion Free Response, n(%)	6 (7.0%)	7 (7.4%)
Censor		
Subjects Censored, n(%)	80 (93.0%)	87 (92.6%)
Non-Responder: Censored at Randomization Date	34 (42.5%)	55 (63.2%)
No Loss of Response: Censored at Last Subject Visit Date at DB Phase	46 (57.5%)	32 (36.8%)
Kaplan-Meier Estimate of Duration of RBC Transfusion Free Response (Weeks)		
25-percentile (95% CI)	NE (12.14, NE)	NE (2.29, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)
Min, Max	0.14, 12.71	0.14, 13.14
Stratified Log-Rank Test p-value	0.16	
Adjusted Hazard Ratio (95% CI)	0.49 (0.16, 1.52)	
Unstratified Log-Rank Test p-value	0.41	
Unadjusted Hazard Ratio (95% CI)	0.63 (0.21, 1.89)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-dur-rbc-tfr.sas V.03.05 Output file: t-dur-rbc-tfr.pdf 24AUG2023:11:03

Table 2.2001: RBC Transfusion-free Rate at Week 24 and Week 12
Double-blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
RBC Transfusion Free Rate at Week 24			
Responder, n(%)	44 (51.2%)	31 (33.0%)	75 (41.7%)
95% Exact CI	0.4014, 0.6210	0.2362, 0.4344	0.3438, 0.4923
Proportion Difference - Stratified CMH Method (95% CI)	0.21 (0.06, 0.35)		
p-value	0.005		
Proportion Difference - Unstratified CMH Method (95% CI)	0.18 (0.04, 0.32)		
p-value	0.013		
Proportion Difference - Unstratified Exact Method (95% CI)	0.18 (0.04, 0.32)		
p-value	0.016		
Unadjusted Inverse Relative Risk (95% CI)	0.64 (0.45, 0.92)		
p-value [1]	0.015		
Unadjusted Inverse Odds Ratio (95% CI)	0.47 (0.26, 0.86)		
p-value [1]	0.014		
Unadjusted Absolute Risk Difference (95% CI)	0.18 (0.04, 0.32)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.61 (0.43, 0.86)		
p-value [2]	0.005		
Non-responder, n(%)	42 (48.8%)	63 (67.0%)	105 (58.3%)
RBC Transfusion within 12 weeks prior to Week 24	26 (30.2%)	55 (58.5%)	81 (45.0%)
Discontinued prior to week 24	16 (18.6%)	8 (8.5%)	24 (13.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

Table 2.2001: RBC Transfusion-free Rate at Week 24 and Week 12
Double-blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
RBC Transfusion Free Rate at Week 12			
Responder, n(%)	38 (44.2%)	25 (26.6%)	63 (35.0%)
95% Exact CI	0.3348, 0.5530	0.1801, 0.3671	0.2805, 0.4245
Proportion Difference - Stratified CMH Method (95% CI)	0.21 (0.08, 0.34)		
p-value	0.002		
Proportion Difference - Unstratified CMH Method (95% CI)	0.18 (0.04, 0.31)		
p-value	0.013		
Proportion Difference - Unstratified Exact Method (95% CI)	0.18 (0.03, 0.32)		
p-value	0.019		
Unadjusted Inverse Relative Risk (95% CI)	0.60 (0.40, 0.91)		
p-value [1]	0.016		
Unadjusted Inverse Odds Ratio (95% CI)	0.46 (0.25, 0.85)		
p-value [1]	0.014		
Unadjusted Absolute Risk Difference (95% CI)	0.18 (0.04, 0.31)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.54 (0.37, 0.80)		
p-value [2]	0.002		
Non-responder, n(%)	48 (55.8%)	69 (73.4%)	117 (65.0%)
RBC Transfusion within 12 weeks prior to Week 12	38 (44.2%)	67 (71.3%)	105 (58.3%)
Discontinued prior to week 12	10 (11.6%)	2 (2.1%)	12 (6.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

Table 2.2101: Analysis of RBC Transfusion Free Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)
RBC Transfusion Free Rate at Baseline in OL Phase			
Responder, n(%)	24 (37.5%)	31 (36.9%)	55 (37.2%)
95% Exact CI	0.2570, 0.5049	0.2663, 0.4813	0.2937, 0.4548
Non-responder, n(%)	40 (62.5%)	53 (63.1%)	93 (62.8%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (RUX->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of the 1st MMB dose in the OL phase
For Continuing (MMB->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of randomization excluding RBC transfusion associated with clinically overt bleeding.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019

Table 2.2101: Analysis of RBC Transfusion Free Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)
Week 12 in OL Phase			
Subjects ongoing and not reaching week 12 in OL phase, n(%)	0	0	0
Subjects included for Transfusion free response rate calculation, n(%)	64 (100.0%)	84 (100.0%)	148 (100.0%)
RBC Transfusion Free Rate at Week 12 in OL Phase			
Responder, n(%)	40 (62.5%)	57 (67.9%)	97 (65.5%)
95% Exact CI	0.4951, 0.7430	0.5678, 0.7764	0.5729, 0.7315
Non-responder, n(%)	24 (37.5%)	27 (32.1%)	51 (34.5%)
RBC Transfusion within 12 weeks prior to week 12 in OL phase	20 (31.3%)	17 (20.2%)	37 (25.0%)
Discontinued prior to week 12	4 (6.3%)	10 (11.9%)	14 (9.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (RUX->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of the 1st MMB dose in the OL phase
For Continuing (MMB->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of randomization excluding RBC transfusion associated with clinically overt bleeding.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019

Table 2.2101: Analysis of RBC Transfusion Free Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)
Week 24 in OL Phase			
Subjects ongoing and not reaching week 24 in OL phase, n(%)	0	0	0
Subjects included for Transfusion free response rate calculation, n(%)	64 (100.0%)	84 (100.0%)	148 (100.0%)
RBC Transfusion Free Rate at Week 24 in OL Phase			
Responder, n(%)	40 (62.5%)	50 (59.5%)	90 (60.8%)
95% Exact CI	0.4951, 0.7430	0.4825, 0.7010	0.5246, 0.6872
Non-responder, n(%)	24 (37.5%)	34 (40.5%)	58 (39.2%)
RBC Transfusion within 12 weeks prior to week 24 in OL phase	16 (25.0%)	19 (22.6%)	35 (23.6%)
Discontinued prior to week 24	8 (12.5%)	15 (17.9%)	23 (15.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (RUX->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of the 1st MMB dose in the OL phase
For Continuing (MMB->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of randomization excluding RBC transfusion associated with clinically overt bleeding.
RBC = Red Blood Cell

Table 2.2101: Analysis of RBC Transfusion Free Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)
Week 36 in OL Phase			
Subjects ongoing and not reaching week 36 in OL phase, n(%)	0	0	0
Subjects included for Transfusion free response rate calculation, n(%)	64 (100.0%)	84 (100.0%)	148 (100.0%)
RBC Transfusion Free Rate at Week 36 in OL Phase			
Responder, n(%)	35 (54.7%)	50 (59.5%)	85 (57.4%)
95% Exact CI	0.4175, 0.6718	0.4825, 0.7010	0.4905, 0.6551
Non-responder, n(%)	29 (45.3%)	34 (40.5%)	63 (42.6%)
RBC Transfusion within 12 weeks prior to week 36 in OL phase	17 (26.6%)	12 (14.3%)	29 (19.6%)
Discontinued prior to week 36	12 (18.8%)	22 (26.2%)	34 (23.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (RUX->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of the 1st MMB dose in the OL phase
For Continuing (MMB->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of randomization excluding RBC transfusion associated with clinically overt bleeding.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019

Table 2.2101: Analysis of RBC Transfusion Free Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)
Week 48 in OL Phase			
Subjects ongoing and not reaching week 48 in OL phase, n(%)	0	0	0
Subjects included for Transfusion free response rate calculation, n(%)	64 (100.0%)	84 (100.0%)	148 (100.0%)
RBC Transfusion Free Rate at Week 48 in OL Phase			
Responder, n(%)	29 (45.3%)	44 (52.4%)	73 (49.3%)
95% Exact CI	0.3282, 0.5825	0.4119, 0.6340	0.4102, 0.5766
Non-responder, n(%)	35 (54.7%)	40 (47.6%)	75 (50.7%)
RBC Transfusion within 12 weeks prior to week 48 in OL phase	15 (23.4%)	6 (7.1%)	21 (14.2%)
Discontinued prior to week 48	20 (31.3%)	34 (40.5%)	54 (36.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (RUX->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of the 1st MMB dose in the OL phase
For Continuing (MMB->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of randomization excluding RBC transfusion associated with clinically overt bleeding.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019

Table 2.2101: Analysis of RBC Transfusion Free Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)
Week 60 in OL Phase			
Subjects ongoing and not reaching week 60 in OL phase, n(%)	0	0	0
Subjects included for Transfusion free response rate calculation, n(%)	64 (100.0%)	84 (100.0%)	148 (100.0%)
RBC Transfusion Free Rate at Week 60 in OL Phase			
Responder, n(%)	23 (35.9%)	38 (45.2%)	61 (41.2%)
95% Exact CI	0.2432, 0.4890	0.3434, 0.5648	0.3320, 0.4959
Non-responder, n(%)	41 (64.1%)	46 (54.8%)	87 (58.8%)
RBC Transfusion within 12 weeks prior to week 60 in OL phase	16 (25.0%)	7 (8.3%)	23 (15.5%)
Discontinued prior to week 60	25 (39.1%)	39 (46.4%)	64 (43.2%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (RUX->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of the 1st MMB dose in the OL phase
For Continuing (MMB->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of randomization excluding RBC transfusion associated with clinically overt bleeding.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-rbc-tfr-ol.sas V.03.05 Output file: t-rbc-tfr-ol.pdf 29AUG2023: 9:45

Table 2.2101: Analysis of RBC Transfusion Free Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)
Week 72 in OL Phase			
Subjects ongoing and not reaching week 72 in OL phase, n(%)	0	0	0
Subjects included for Transfusion free response rate calculation, n(%)	64 (100.0%)	84 (100.0%)	148 (100.0%)
RBC Transfusion Free Rate at Week 72 in OL Phase			
Responder, n(%)	24 (37.5%)	34 (40.5%)	58 (39.2%)
95% Exact CI	0.2570, 0.5049	0.2990, 0.5175	0.3128, 0.4754
Non-responder, n(%)	40 (62.5%)	50 (59.5%)	90 (60.8%)
RBC Transfusion within 12 weeks prior to week 72 in OL phase	9 (14.1%)	8 (9.5%)	17 (11.5%)
Discontinued prior to week 72	31 (48.4%)	42 (50.0%)	73 (49.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (RUX->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of the 1st MMB dose in the OL phase
For Continuing (MMB->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of randomization excluding RBC transfusion associated with clinically overt bleeding.
RBC = Red Blood Cell

Table 2.2101: Analysis of RBC Transfusion Free Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)
Week 84 in OL Phase			
Subjects ongoing and not reaching week 84 in OL phase, n(%)	0	0	0
Subjects included for Transfusion free response rate calculation, n(%)	64 (100.0%)	84 (100.0%)	148 (100.0%)
RBC Transfusion Free Rate at Week 84 in OL Phase			
Responder, n(%)	23 (35.9%)	28 (33.3%)	51 (34.5%)
95% Exact CI	0.2432, 0.4890	0.2342, 0.4446	0.2685, 0.4271
Non-responder, n(%)	41 (64.1%)	56 (66.7%)	97 (65.5%)
RBC Transfusion within 12 weeks prior to week 84 in OL phase	7 (10.9%)	6 (7.1%)	13 (8.8%)
Discontinued prior to week 84	34 (53.1%)	50 (59.5%)	84 (56.8%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (RUX->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of the 1st MMB dose in the OL phase
For Continuing (MMB->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of randomization excluding RBC transfusion associated with clinically overt bleeding.
RBC = Red Blood Cell

Table 2.2101: Analysis of RBC Transfusion Free Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)
Week 96 in OL Phase			
Subjects ongoing and not reaching week 96 in OL phase, n(%)	0	0	0
Subjects included for Transfusion free response rate calculation, n(%)	64 (100.0%)	84 (100.0%)	148 (100.0%)
RBC Transfusion Free Rate at Week 96 in OL Phase			
Responder, n(%)	20 (31.3%)	30 (35.7%)	50 (33.8%)
95% Exact CI	0.2024, 0.4406	0.2555, 0.4692	0.2622, 0.4201
Non-responder, n(%)	44 (68.8%)	54 (64.3%)	98 (66.2%)
RBC Transfusion within 12 weeks prior to week 96 in OL phase	7 (10.9%)	3 (3.6%)	10 (6.8%)
Discontinued prior to week 96	37 (57.8%)	51 (60.7%)	88 (59.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (RUX->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of the 1st MMB dose in the OL phase
For Continuing (MMB->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of randomization excluding RBC transfusion associated with clinically overt bleeding.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-rbc-tfr-ol.sas V.03.05 Output file: t-rbc-tfr-ol.pdf 29AUG2023: 9:45

Table 2.2101: Analysis of RBC Transfusion Free Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)
Week 108 in OL Phase			
Subjects ongoing and not reaching week 108 in OL phase, n(%)	0	0	0
Subjects included for Transfusion free response rate calculation, n(%)	64 (100.0%)	84 (100.0%)	148 (100.0%)
RBC Transfusion Free Rate at Week 108 in OL Phase			
Responder, n(%)	14 (21.9%)	29 (34.5%)	43 (29.1%)
95% Exact CI	0.1251, 0.3397	0.2448, 0.4569	0.2189, 0.3708
Non-responder, n(%)	50 (78.1%)	55 (65.5%)	105 (70.9%)
RBC Transfusion within 12 weeks prior to week 108 in OL phase	9 (14.1%)	4 (4.8%)	13 (8.8%)
Discontinued prior to week 108	41 (64.1%)	51 (60.7%)	92 (62.2%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (RUX->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of the 1st MMB dose in the OL phase
For Continuing (MMB->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of randomization excluding RBC transfusion associated with clinically overt bleeding.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019

Table 2.2101: Analysis of RBC Transfusion Free Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)
Week 120 in OL Phase			
Subjects ongoing and not reaching week 120 in OL phase, n(%)	0	0	0
Subjects included for Transfusion free response rate calculation, n(%)	64 (100.0%)	84 (100.0%)	148 (100.0%)
RBC Transfusion Free Rate at Week 120 in OL Phase			
Responder, n(%)	14 (21.9%)	24 (28.6%)	38 (25.7%)
95% Exact CI	0.1251, 0.3397	0.1924, 0.3947	0.1885, 0.3350
Non-responder, n(%)	50 (78.1%)	60 (71.4%)	110 (74.3%)
RBC Transfusion within 12 weeks prior to week 120 in OL phase	6 (9.4%)	4 (4.8%)	10 (6.8%)
Discontinued prior to week 120	44 (68.8%)	56 (66.7%)	100 (67.6%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (RUX->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of the 1st MMB dose in the OL phase
For Continuing (MMB->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of randomization excluding RBC transfusion associated with clinically overt bleeding.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019

Table 2.2101: Analysis of RBC Transfusion Free Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)
Week 132 in OL Phase			
Subjects ongoing and not reaching week 132 in OL phase, n(%)	0	0	0
Subjects included for Transfusion free response rate calculation, n(%)	64 (100.0%)	84 (100.0%)	148 (100.0%)
RBC Transfusion Free Rate at Week 132 in OL Phase			
Responder, n(%)	14 (21.9%)	22 (26.2%)	36 (24.3%)
95% Exact CI	0.1251, 0.3397	0.1720, 0.3693	0.1765, 0.3205
Non-responder, n(%)	50 (78.1%)	62 (73.8%)	112 (75.7%)
RBC Transfusion within 12 weeks prior to week 132 in OL phase	3 (4.7%)	0	3 (2.0%)
Discontinued prior to week 132	47 (73.4%)	62 (73.8%)	109 (73.6%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (RUX->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of the 1st MMB dose in the OL phase
For Continuing (MMB->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of randomization excluding RBC transfusion associated with clinically overt bleeding.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019

Table 2.2101: Analysis of RBC Transfusion Free Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)
Week 144 in OL Phase			
Subjects ongoing and not reaching week 144 in OL phase, n(%)	0	0	0
Subjects included for Transfusion free response rate calculation, n(%)	64 (100.0%)	84 (100.0%)	148 (100.0%)
RBC Transfusion Free Rate at Week 144 in OL Phase			
Responder, n(%)	10 (15.6%)	13 (15.5%)	23 (15.5%)
95% Exact CI	0.0776, 0.2686	0.0851, 0.2501	0.1011, 0.2240
Non-responder, n(%)	54 (84.4%)	71 (84.5%)	125 (84.5%)
RBC Transfusion within 12 weeks prior to week 144 in OL phase	3 (4.7%)	1 (1.2%)	4 (2.7%)
Discontinued prior to week 144	51 (79.7%)	70 (83.3%)	121 (81.8%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (RUX->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of the 1st MMB dose in the OL phase
For Continuing (MMB->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of randomization excluding RBC transfusion associated with clinically overt bleeding.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019

Table 2.2101: Analysis of RBC Transfusion Free Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)
Week 156 in OL Phase			
Subjects ongoing and not reaching week 156 in OL phase, n(%)	0	0	0
Subjects included for Transfusion free response rate calculation, n(%)	64 (100.0%)	84 (100.0%)	148 (100.0%)
RBC Transfusion Free Rate at Week 156 in OL Phase			
Responder, n(%)	4 (6.3%)	6 (7.1%)	10 (6.8%)
95% Exact CI	0.0173, 0.1524	0.0267, 0.1490	0.0329, 0.1207
Non-responder, n(%)	60 (93.8%)	78 (92.9%)	138 (93.2%)
RBC Transfusion within 12 weeks prior to week 156 in OL phase	2 (3.1%)	0	2 (1.4%)
Discontinued prior to week 156	58 (90.6%)	78 (92.9%)	136 (91.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (RUX->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of the 1st MMB dose in the OL phase
For Continuing (MMB->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of randomization excluding RBC transfusion associated with clinically overt bleeding.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019

Table 2.2101: Analysis of RBC Transfusion Free Response
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)
Week 168 in OL Phase			
Subjects ongoing and not reaching week 168 in OL phase, n(%)	0	0	0
Subjects included for Transfusion free response rate calculation, n(%)	64 (100.0%)	84 (100.0%)	148 (100.0%)
RBC Transfusion Free Rate at Week 168 in OL Phase			
Responder, n(%)	5 (7.8%)	2 (2.4%)	7 (4.7%)
95% Exact CI	0.0259, 0.1730	0.0029, 0.0834	0.0192, 0.0950
Non-responder, n(%)	59 (92.2%)	82 (97.6%)	141 (95.3%)
RBC Transfusion within 12 weeks prior to week 168 in OL phase	1 (1.6%)	0	1 (0.7%)
Discontinued prior to week 168	58 (90.6%)	82 (97.6%)	140 (94.6%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (RUX->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of the 1st MMB dose in the OL phase
For Continuing (MMB->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of randomization excluding RBC transfusion associated with clinically overt bleeding.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019

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Table 2.4602: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Age
Double-blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Any Type Transfusion Free Rate at Week 24					
Responder, n(%)	9 (37.5%)	12 (33.3%)	22 (35.5%)	7 (12.1%)	
95% Exact CI	0.1880, 0.5941	0.1856, 0.5097	0.2374, 0.4866	0.0499, 0.2330	
Proportion Difference - Stratified CMH Method (95% CI)	0.03 (-0.26, 0.31)		0.27 (0.12, 0.42)		
p-value	0.84		<0.001		
Proportion Difference - Unstratified CMH Method (95% CI)	0.04 (-0.21, 0.29)		0.23 (0.09, 0.38)		
p-value	0.75		0.002		
Proportion Difference - Unstratified Exact Method (95% CI)	0.04 (-0.22, 0.30)		0.23 (0.05, 0.40)		
p-value	0.79		0.003		
Unadjusted Inverse Relative Risk (95% CI)	0.89 (0.44, 1.78)		0.34 (0.16, 0.74)		
p-value [1]	0.74		0.006		
Unadjusted interaction test for Treatment*Age Group [3]					0.060
Unadjusted Inverse Odds Ratio (95% CI)	0.83 (0.28, 2.45)		0.25 (0.10, 0.64)		
p-value [1]	0.74		0.004		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.21, 0.29)		0.23 (0.09, 0.38)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.92 (0.47, 1.81)		NE		
p-value [2]	0.82		NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes,no), and baseline platelet count (<100,100-200,>200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-at-tf-at24-rt-gba.sas V.03.05 Output file: t-sg-at-tf-at24-rt-gba-age.pdf 29AUG2023: 9:36

Table 2.4602: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Age
Double-blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Adjusted interaction test for Treatment*Age Group [3]					0.046
Non-responder, n(%)	15 (62.5%)	24 (66.7%)	40 (64.5%)	51 (87.9%)	
Any Type Transfusion within 12 weeks prior to Week 24	11 (45.8%)	21 (58.3%)	28 (45.2%)	46 (79.3%)	
Discontinued prior to week 24	4 (16.7%)	3 (8.3%)	12 (19.4%)	5 (8.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes,no), and baseline platelet count (<100,100-200,>200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.4607: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline Hemoglobin Level
Double-blind Phase
ITT-Anemic Analysis Set

	HGB <8g/dL		HGB >=8g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Any Type Transfusion Free Rate at Week 24					
Responder, n(%)	5 (17.9%)	2 (9.5%)	26 (44.8%)	17 (23.3%)	
95% Exact CI	0.0606, 0.3689	0.0117, 0.3038	0.3174, 0.5846	0.1419, 0.3465	
Proportion Difference - Stratified CMH Method (95% CI)	0.08 (-0.14, 0.30)		0.23 (0.07, 0.39)		
p-value	0.49		0.005		
Proportion Difference - Unstratified CMH Method (95% CI)	0.08 (-0.12, 0.29)		0.22 (0.05, 0.38)		
p-value	0.42		0.009		
Proportion Difference - Unstratified Exact Method (95% CI)	0.08 (-0.20, 0.36)		0.22 (0.04, 0.38)		
p-value	0.68		0.014		
Unadjusted Inverse Relative Risk (95% CI)	0.53 (0.11, 2.49)		0.52 (0.31, 0.86)		
p-value [1]	0.42		0.011		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.97
Unadjusted Inverse Odds Ratio (95% CI)	0.48 (0.08, 2.78)		0.37 (0.18, 0.79)		
p-value [1]	0.42		0.010		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.11, 0.27)		0.22 (0.05, 0.38)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.55 (0.12, 2.55)		0.49 (0.30, 0.80)		
p-value [2]	0.44		0.004		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.90

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes,no), and baseline platelet count (<100,100-200,>200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-at-tf-at24-rt-gba.sas V.03.05 Output file: t-sg-at-tf-at24-rt-gba-hgb.pdf 29AUG2023: 9:36

Table 2.4607: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline Hemoglobin Level
Double-blind Phase
ITT-Anemic Analysis Set

	HGB <8g/dL		HGB >=8g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Non-responder, n(%)	23 (82.1%)	19 (90.5%)	32 (55.2%)	56 (76.7%)	
Any Type Transfusion within 12 weeks prior to Week 24	17 (60.7%)	15 (71.4%)	22 (37.9%)	52 (71.2%)	
Discontinued prior to week 24	6 (21.4%)	4 (19.0%)	10 (17.2%)	4 (5.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes,no), and baseline platelet count (<100,100-200,>200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

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Table 2.4606: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline IPSS Two-Level Risk

Double-blind Phase

ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Any Type Transfusion Free Rate at Week 24					
Responder, n(%)	12 (42.9%)	7 (29.2%)	19 (32.8%)	12 (17.1%)	
95% Exact CI	0.2446, 0.6282	0.1262, 0.5109	0.2101, 0.4634	0.0918, 0.2803	
Proportion Difference - Stratified CMH Method (95% CI)	0.21 (-0.08, 0.49)		0.17 (0.02, 0.32)		
p-value	0.15		0.030		
Proportion Difference - Unstratified CMH Method (95% CI)	0.14 (-0.13, 0.40)		0.16 (0.00, 0.31)		
p-value	0.31		0.044		
Proportion Difference - Unstratified Exact Method (95% CI)	0.14 (-0.14, 0.40)		0.16 (-0.02, 0.32)		
p-value	0.39		0.061		
Unadjusted Inverse Relative Risk (95% CI)	0.68 (0.32, 1.45)		0.52 (0.28, 0.99)		
p-value [1]	0.32		0.045		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.61
Unadjusted Inverse Odds Ratio (95% CI)	0.55 (0.17, 1.74)		0.42 (0.19, 0.97)		
p-value [1]	0.31		0.043		
Unadjusted Absolute Risk Difference (95% CI)	0.14 (-0.12, 0.40)		0.16 (0.01, 0.31)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes,no), and baseline platelet count (<100,100-200,>200 10^9/L) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.4606: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline IPSS Two-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.74
Non-responder, n(%)	16 (57.1%)	17 (70.8%)	39 (67.2%)	58 (82.9%)	
Any Type Transfusion within 12 weeks prior to Week 24	12 (42.9%)	15 (62.5%)	27 (46.6%)	52 (74.3%)	
Discontinued prior to week 24	4 (14.3%)	2 (8.3%)	12 (20.7%)	6 (8.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes,no), and baseline platelet count (<100,100-200,>200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019

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Table 2.4605: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Any Type Transfusion Free Rate at Week 24				
Responder, n(%)	2 (100.0%)	1 (25.0%)	10 (38.5%)	6 (30.0%)
95% Exact CI	0.1581, 1.0000	0.0063, 0.8059	0.2023, 0.5943	0.1189, 0.5428
Proportion Difference - Stratified CMH Method (95% CI)	0.50 (-0.72, 1.72)		0.16 (-0.12, 0.45)	
p-value	0.42		0.26	
Proportion Difference - Unstratified CMH Method (95% CI)	0.75 (-0.15, 1.65)		0.08 (-0.20, 0.37)	
p-value	0.10		0.56	
Proportion Difference - Unstratified Exact Method (95% CI)	0.75 (-0.23, 0.99)		0.08 (-0.21, 0.36)	
p-value	0.40		0.76	
Unadjusted Inverse Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes,no), and baseline platelet count (<100,100-200,>200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.4605: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=58)	High Risk RUX (N=70)	p-value
Any Type Transfusion Free Rate at Week 24			
Responder, n(%)	19 (32.8%)	12 (17.1%)	
95% Exact CI	0.2101, 0.4634	0.0918, 0.2803	
Proportion Difference - Stratified CMH Method (95% CI)	0.17 (0.02, 0.32)		
p-value	0.030		
Proportion Difference - Unstratified CMH Method (95% CI)	0.16 (0.00, 0.31)		
p-value	0.044		
Proportion Difference - Unstratified Exact Method (95% CI)	0.16 (-0.02, 0.32)		
p-value	0.061		
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes,no), and baseline platelet count (<100,100-200,>200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.4605: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Non-responder, n(%)	0	3 (75.0%)	16 (61.5%)	14 (70.0%)
Any Type Transfusion within 12 weeks prior to Week 24	0	3 (75.0%)	12 (46.2%)	12 (60.0%)
Discontinued prior to week 24	0	0	4 (15.4%)	2 (10.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes,no), and baseline platelet count (<100,100-200,>200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.4605: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	High Risk		
(Continued)	MMB (N=58)	RUX (N=70)	p-value
Non-responder, n(%)	39 (67.2%)	58 (82.9%)	
Any Type Transfusion within 12 weeks prior to Week 24	27 (46.6%)	52 (74.3%)	
Discontinued prior to week 24	12 (20.7%)	6 (8.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes,no), and baseline platelet count (<100,100-200,>200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

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Table 2.4608: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline MF Disease Status

Double-blind Phase

ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Any Type Transfusion Free Rate at Week 24				
Responder, n(%)	22 (37.3%)	11 (20.4%)	4 (25.0%)	7 (25.0%)
95% Exact CI	0.2504, 0.5085	0.1063, 0.3353	0.0727, 0.5238	0.1069, 0.4487
Proportion Difference - Stratified CMH Method (95% CI)	0.18 (0.01, 0.34)		0.07 (-0.22, 0.36)	
p-value	0.034		0.63	
Proportion Difference - Unstratified CMH Method (95% CI)	0.17 (0.00, 0.34)		0.00 (-0.28, 0.28)	
p-value	0.046		1.00	
Proportion Difference - Unstratified Exact Method (95% CI)	0.17 (-0.02, 0.35)		0.00 (-0.30, 0.30)	
p-value	0.063		1.00	
Unadjusted Inverse Relative Risk (95% CI)	0.55 (0.29, 1.02)		1.00 (0.35, 2.90)	
p-value [1]	0.057		1.00	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.43 (0.18, 1.00)		1.00 (0.24, 4.13)	
p-value [1]	0.051		1.00	
Unadjusted Absolute Risk Difference (95% CI)	0.17 (0.01, 0.33)		0.00 (-0.27, 0.27)	
Adjusted Inverse Relative Risk (95% CI) [2]	0.54 (0.29, 0.99)		NE	
p-value [2]	0.045		NE	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes,no), and baseline platelet count (<100,100-200,>200 10^9/L) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.4608: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=11)	Post-PV Myelofibrosis RUX (N=12)	p-value
Any Type Transfusion Free Rate at Week 24			
Responder, n(%)	5 (45.5%)	1 (8.3%)	
95% Exact CI	0.1675, 0.7662	0.0021, 0.3848	
Proportion Difference - Stratified CMH Method (95% CI)	0.48 (0.07, 0.89)		
p-value	0.021		
Proportion Difference - Unstratified CMH Method (95% CI)	0.37 (0.01, 0.73)		
p-value	0.044		
Proportion Difference - Unstratified Exact Method (95% CI)	0.37 (-0.06, 0.70)		
p-value	0.069		
Unadjusted Inverse Relative Risk (95% CI)	0.18 (0.03, 1.33)		
p-value [1]	0.094		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.21
Unadjusted Inverse Odds Ratio (95% CI)	0.11 (0.01, 1.16)		
p-value [1]	0.066		
Unadjusted Absolute Risk Difference (95% CI)	0.37 (0.04, 0.70)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes,no), and baseline platelet count (<100,100-200,>200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Table 2.4608: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-responder, n(%)	37 (62.7%)	43 (79.6%)	12 (75.0%)	21 (75.0%)
Any Type Transfusion within 12 weeks prior to Week 24	27 (45.8%)	39 (72.2%)	9 (56.3%)	19 (67.9%)
Discontinued prior to week 24	10 (16.9%)	4 (7.4%)	3 (18.8%)	2 (7.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes,no), and baseline platelet count (<100,100-200,>200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.4608: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=11)	Post-PV Myelofibrosis RUX (N=12)	p-value
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.085
Non-responder, n(%)	6 (54.5%)	11 (91.7%)	
Any Type Transfusion within 12 weeks prior to Week 24	3 (27.3%)	9 (75.0%)	
Discontinued prior to week 24	3 (27.3%)	2 (16.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes,no), and baseline platelet count (<100,100-200,>200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019

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Table 2.4604: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Region
Double-blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Any Type Transfusion Free Rate at Week 24					
Responder, n(%)	15 (28.3%)	9 (17.6%)	16 (48.5%)	10 (23.3%)	
95% Exact CI	0.1679, 0.4235	0.0840, 0.3087	0.3080, 0.6646	0.1176, 0.3863	
Proportion Difference - Stratified CMH Method (95% CI)	0.18 (0.01, 0.35)		0.25 (0.04, 0.46)		
p-value	0.037		0.019		
Proportion Difference - Unstratified CMH Method (95% CI)	0.11 (-0.06, 0.27)		0.25 (0.04, 0.47)		
p-value	0.20		0.022		
Proportion Difference - Unstratified Exact Method (95% CI)	0.11 (-0.09, 0.29)		0.25 (0.03, 0.46)		
p-value	0.25		0.029		
Unadjusted Inverse Relative Risk (95% CI)	0.62 (0.30, 1.30)		0.48 (0.25, 0.92)		
p-value [1]	0.21		0.026		
Unadjusted interaction test for Treatment*Region [3]					0.60
Unadjusted Inverse Odds Ratio (95% CI)	0.54 (0.21, 1.38)		0.32 (0.12, 0.86)		
p-value [1]	0.20		0.024		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.05, 0.27)		0.25 (0.04, 0.46)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.46 (0.23, 0.89)		NE		
p-value [2]	0.020		NE		
Adjusted interaction test for Treatment*Region [3]					0.88

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes,no), and baseline platelet count (<100,100-200,>200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.4604: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Region
Double-blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Non-responder, n(%)	38 (71.7%)	42 (82.4%)	17 (51.5%)	33 (76.7%)	
Any Type Transfusion within 12 weeks prior to Week 24	28 (52.8%)	37 (72.5%)	11 (33.3%)	30 (69.8%)	
Discontinued prior to week 24	10 (18.9%)	5 (9.8%)	6 (18.2%)	3 (7.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes,no), and baseline platelet count (<100,100-200,>200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-at-tf-at24-rt-gba.sas V.03.05 Output file: t-sg-at-tf-at24-rt-gba-reg.pdf 29AUG2023: 9:36

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Table 2.4603: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Gender
Double-blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Any Type Transfusion Free Rate at Week 24					
Responder, n(%)	15 (30.0%)	9 (16.1%)	16 (44.4%)	10 (26.3%)	
95% Exact CI	0.1786, 0.4461	0.0762, 0.2833	0.2794, 0.6190	0.1340, 0.4310	
Proportion Difference - Stratified CMH Method (95% CI)	0.20 (0.03, 0.37)		0.14 (-0.09, 0.37)		
p-value	0.019		0.23		
Proportion Difference - Unstratified CMH Method (95% CI)	0.14 (-0.02, 0.30)		0.18 (-0.04, 0.40)		
p-value	0.092		0.10		
Proportion Difference - Unstratified Exact Method (95% CI)	0.14 (-0.05, 0.32)		0.18 (-0.05, 0.39)		
p-value	0.11		0.14		
Unadjusted Inverse Relative Risk (95% CI)	0.54 (0.26, 1.12)		0.59 (0.31, 1.13)		
p-value [1]	0.095		0.11		
Unadjusted interaction test for Treatment*Gender [3]					0.84
Unadjusted Inverse Odds Ratio (95% CI)	0.45 (0.18, 1.14)		0.45 (0.17, 1.19)		
p-value [1]	0.091		0.11		
Unadjusted Absolute Risk Difference (95% CI)	0.14 (-0.02, 0.30)		0.18 (-0.03, 0.40)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.41 (0.20, 0.82)		NE		
p-value [2]	0.012		NE		
Adjusted interaction test for Treatment*Gender [3]					0.36

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes,no), and baseline platelet count (<100,100-200,>200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.4603: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Gender
Double-blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Non-responder, n(%)	35 (70.0%)	47 (83.9%)	20 (55.6%)	28 (73.7%)	
Any Type Transfusion within 12 weeks prior to Week 24	29 (58.0%)	41 (73.2%)	10 (27.8%)	26 (68.4%)	
Discontinued prior to week 24	6 (12.0%)	6 (10.7%)	10 (27.8%)	2 (5.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes,no), and baseline platelet count (<100,100-200,>200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019

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Table 2.4610: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline Spleen Volume

Double-blind Phase

ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Any Type Transfusion Free Rate at Week 24					
Responder, n(%)	21 (44.7%)	8 (18.6%)	10 (25.6%)	11 (21.6%)	
95% Exact CI	0.3017, 0.5988	0.0839, 0.3340	0.1304, 0.4213	0.1129, 0.3532	
Proportion Difference - Stratified CMH Method (95% CI)	0.29 (0.09, 0.48)		0.07 (-0.12, 0.27)		
p-value	0.003		0.46		
Proportion Difference - Unstratified CMH Method (95% CI)	0.26 (0.07, 0.45)		0.04 (-0.14, 0.22)		
p-value	0.006		0.66		
Proportion Difference - Unstratified Exact Method (95% CI)	0.26 (0.05, 0.45)		0.04 (-0.17, 0.25)		
p-value	0.012		0.80		
Unadjusted Inverse Relative Risk (95% CI)	0.42 (0.21, 0.84)		0.84 (0.40, 1.78)		
p-value [1]	0.014		0.65		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.17
Unadjusted Inverse Odds Ratio (95% CI)	0.28 (0.11, 0.74)		0.80 (0.30, 2.13)		
p-value [1]	0.010		0.65		
Unadjusted Absolute Risk Difference (95% CI)	0.26 (0.08, 0.44)		0.04 (-0.14, 0.22)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.74 (0.36, 1.52)		
p-value [2]	NE		0.41		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes,no), and baseline platelet count (<100,100-200,>200 10^9/L) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.4610: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.32
Non-responder, n(%)	26 (55.3%)	35 (81.4%)	29 (74.4%)	40 (78.4%)	
Any Type Transfusion within 12 weeks prior to Week 24	19 (40.4%)	31 (72.1%)	20 (51.3%)	36 (70.6%)	
Discontinued prior to week 24	7 (14.9%)	4 (9.3%)	9 (23.1%)	4 (7.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes,no), and baseline platelet count (<100,100-200,>200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-at-tf-at24-rt-gba.sas V.03.05 Output file: t-sg-at-tf-at24-rt-gba-spv.pdf 29AUG2023: 9:37

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Table 2.4609: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline TSS
Double-blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Any Type Transfusion Free Rate at Week 24					
Responder, n(%)	17 (38.6%)	11 (20.0%)	14 (34.1%)	8 (21.1%)	
95% Exact CI	0.2436, 0.5450	0.1043, 0.3297	0.2008, 0.5059	0.0955, 0.3732	
Proportion Difference - Stratified CMH Method (95% CI)	0.23 (0.04, 0.41)		0.15 (-0.05, 0.35)		
p-value	0.016		0.14		
Proportion Difference - Unstratified CMH Method (95% CI)	0.19 (0.01, 0.37)		0.13 (-0.07, 0.33)		
p-value	0.044		0.20		
Proportion Difference - Unstratified Exact Method (95% CI)	0.19 (-0.01, 0.38)		0.13 (-0.09, 0.34)		
p-value	0.047		0.22		
Unadjusted Inverse Relative Risk (95% CI)	0.52 (0.27, 0.99)		0.62 (0.29, 1.30)		
p-value [1]	0.046		0.21		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.73
Unadjusted Inverse Odds Ratio (95% CI)	0.40 (0.16, 0.97)		0.51 (0.19, 1.42)		
p-value [1]	0.044		0.20		
Unadjusted Absolute Risk Difference (95% CI)	0.19 (0.01, 0.36)		0.13 (-0.06, 0.33)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.57 (0.29, 1.14)		
p-value [2]	NE		0.11		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes,no), and baseline platelet count (<100,100-200,>200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.4609: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline TSS
Double-blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.57
Non-responder, n(%)	27 (61.4%)	44 (80.0%)	27 (65.9%)	30 (78.9%)	
Any Type Transfusion within 12 weeks prior to Week 24	24 (54.5%)	40 (72.7%)	14 (34.1%)	26 (68.4%)	
Discontinued prior to week 24	3 (6.8%)	4 (7.3%)	13 (31.7%)	4 (10.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes,no), and baseline platelet count (<100,100-200,>200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019

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Table 2.4102: Analysis of Rate of Any Type Transfusion Free Response by Week 24 by Age
Double-blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Any Type Transfusion Free Rate by Week 24 in DB Phase					
Responder, n(%)	14 (58.3%)	26 (72.2%)	28 (45.2%)	29 (50.0%)	
Unadjusted Inverse Relative Risk (95% CI)	1.24 (0.83, 1.84)		1.11 (0.76, 1.61)		
p-value [1]	0.29		0.60		
Unadjusted interaction test for Treatment*Age Group [3]					0.69
Unadjusted Inverse Odds Ratio (95% CI)	1.86 (0.62, 5.53)		1.21 (0.59, 2.49)		
p-value [1]	0.27		0.60		
Unadjusted Absolute Risk Difference (95% CI)	-0.14 (-0.38, 0.11)		-0.05 (-0.23, 0.13)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.35 (0.95, 1.92)		0.88 (0.66, 1.17)		
p-value [2]	0.095		0.37		
Adjusted interaction test for Treatment*Age Group [3]					0.13
Subjects not Transfusion Free at Baseline, n	13	13	43	31	
New Any Type Transfusion Free Rate by Week 24					
Responder, n/N(%)	3/13 (23.1%)	3/13 (23.1%)	9/43 (20.9%)	2/31 (6.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-atf-by24-db-gba.sas V.03.05 Output file: t-sg-atf-by24-db-gba-age.pdf 29AUG2023: 9:00

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Table 2.4107: Analysis of Rate of Any Type Transfusion Free Response by Week 24 by Baseline Hemoglobin Level
Double-blind Phase
ITT-Anemic Analysis Set

	HGB <8g/dL		HGB >=8g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Any Type Transfusion Free Rate by Week 24 in DB Phase					
Responder, n(%)	7 (25.0%)	7 (33.3%)	35 (60.3%)	48 (65.8%)	
Unadjusted Inverse Relative Risk (95% CI)	1.33 (0.55, 3.22)		1.09 (0.83, 1.42)		
p-value [1]	0.52		0.53		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.67
Unadjusted Inverse Odds Ratio (95% CI)	1.50 (0.43, 5.22)		1.26 (0.62, 2.58)		
p-value [1]	0.52		0.52		
Unadjusted Absolute Risk Difference (95% CI)	-0.08 (-0.34, 0.17)		-0.05 (-0.22, 0.11)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.34 (0.55, 3.24)		1.04 (0.84, 1.30)		
p-value [2]	0.52		0.72		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.58
Subjects not Transfusion Free at Baseline, n	25	16	31	28	
New Any Type Transfusion Free Rate by Week 24					
Responder, n/N(%)	4/25 (16.0%)	2/16 (12.5%)	8/31 (25.8%)	3/28 (10.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
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Table 2.4106: Analysis of Rate of Any Type Transfusion Free Response by Week 24 by Baseline IPSS Two-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Any Type Transfusion Free Rate by Week 24 in DB Phase					
Responder, n(%)	16 (57.1%)	17 (70.8%)	26 (44.8%)	38 (54.3%)	
Unadjusted Inverse Relative Risk (95% CI)	1.24 (0.82, 1.87)		1.21 (0.85, 1.73)		
p-value [1]	0.31		0.29		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.93
Unadjusted Inverse Odds Ratio (95% CI)	1.82 (0.57, 5.78)		1.46 (0.73, 2.94)		
p-value [1]	0.31		0.29		
Unadjusted Absolute Risk Difference (95% CI)	-0.14 (-0.40, 0.12)		-0.09 (-0.27, 0.08)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.11 (0.80, 1.53)		1.09 (0.80, 1.48)		
p-value [2]	0.53		0.60		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.88
Subjects not Transfusion Free at Baseline, n	15	7	41	37	
New Any Type Transfusion Free Rate by Week 24					
Responder, n/N(%)	3/15 (20.0%)	0	9/41 (22.0%)	5/37 (13.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

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Table 2.4105: Analysis of Rate of Any Type Transfusion Free Response by Week 24 by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Any Type Transfusion Free Rate by Week 24 in DB Phase				
Responder, n(%)	2 (100.0%)	2 (50.0%)	14 (53.8%)	15 (75.0%)
Unadjusted Inverse Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Subjects not Transfusion Free at Baseline, n	0	2	15	5
New Any Type Transfusion Free Rate by Week 24				
Responder, n/N(%)	0	0	3/15 (20.0%)	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.4105: Analysis of Rate of Any Type Transfusion Free Response by Week 24 by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=58)	High Risk RUX (N=70)	p-value
Any Type Transfusion Free Rate by Week 24 in DB Phase			
Responder, n(%)	26 (44.8%)	38 (54.3%)	
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Subjects not Transfusion Free at Baseline, n	41	37	
New Any Type Transfusion Free Rate by Week 24			
Responder, n/N(%)	9/41 (22.0%)	5/37 (13.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-atf-by24-db-gba.sas V.03.05 Output file: t-sg-atf-by24-db-gba-ip3.pdf 29AUG2023: 9:00

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Table 2.4108: Analysis of Rate of Any Type Transfusion Free Response by Week 24 by Baseline MF Disease Status

Double-blind Phase

ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Any Type Transfusion Free Rate by Week 24 in DB Phase				
Responder, n(%)	28 (47.5%)	31 (57.4%)	9 (56.3%)	19 (67.9%)
Unadjusted Inverse Relative Risk (95% CI)	1.21 (0.85, 1.72)		1.21 (0.73, 1.99)	
p-value [1]	0.29		0.46	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	1.49 (0.71, 3.14)		1.64 (0.46, 5.83)	
p-value [1]	0.29		0.44	
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.28, 0.08)		-0.12 (-0.41, 0.18)	
Adjusted Inverse Relative Risk (95% CI) [2]	1.14 (0.85, 1.53)		NE	
p-value [2]	0.39		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Subjects not Transfusion Free at Baseline, n	38	27	10	10
New Any Type Transfusion Free Rate by Week 24				
Responder, n/N(%)	7/38 (18.4%)	4/27 (14.8%)	3/10 (30.0%)	1/10 (10.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.4108: Analysis of Rate of Any Type Transfusion Free Response by Week 24 by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=11)	Post-PV Myelofibrosis RUX (N=12)	p-value
Any Type Transfusion Free Rate by Week 24 in DB Phase			
Responder, n(%)	5 (45.5%)	5 (41.7%)	
Unadjusted Inverse Relative Risk (95% CI)	0.92 (0.36, 2.33)		
p-value [1]	0.85		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.86
Unadjusted Inverse Odds Ratio (95% CI)	0.86 (0.16, 4.47)		
p-value [1]	0.85		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.37, 0.44)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.43
Subjects not Transfusion Free at Baseline, n	8	7	
New Any Type Transfusion Free Rate by Week 24			
Responder, n/N(%)	2/8 (25.0%)	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
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Table 2.4104: Analysis of Rate of Any Type Transfusion Free Response by Week 24 by Region
Double-blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Any Type Transfusion Free Rate by Week 24 in DB Phase					
Responder, n(%)	22 (41.5%)	26 (51.0%)	20 (60.6%)	29 (67.4%)	
Unadjusted Inverse Relative Risk (95% CI)	1.23 (0.81, 1.87)		1.11 (0.79, 1.57)		
p-value [1]	0.33		0.54		
Unadjusted interaction test for Treatment*Region [3]					0.72
Unadjusted Inverse Odds Ratio (95% CI)	1.47 (0.68, 3.18)		1.35 (0.52, 3.47)		
p-value [1]	0.33		0.54		
Unadjusted Absolute Risk Difference (95% CI)	-0.09 (-0.29, 0.10)		-0.07 (-0.29, 0.15)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.95 (0.70, 1.29)		1.13 (0.82, 1.55)		
p-value [2]	0.72		0.45		
Adjusted interaction test for Treatment*Region [3]					0.64
Subjects not Transfusion Free at Baseline, n	40	27	16	17	
New Any Type Transfusion Free Rate by Week 24					
Responder, n/N(%)	9/40 (22.5%)	2/27 (7.4%)	3/16 (18.8%)	3/17 (17.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

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Table 2.4103: Analysis of Rate of Any Type Transfusion Free Response by Week 24 by Gender
Double-blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Any Type Transfusion Free Rate by Week 24 in DB Phase					
Responder, n(%)	19 (38.0%)	27 (48.2%)	23 (63.9%)	28 (73.7%)	
Unadjusted Inverse Relative Risk (95% CI)	1.27 (0.81, 1.98)		1.15 (0.85, 1.57)		
p-value [1]	0.30		0.37		
Unadjusted interaction test for Treatment*Gender [3]					0.73
Unadjusted Inverse Odds Ratio (95% CI)	1.52 (0.70, 3.30)		1.58 (0.59, 4.27)		
p-value [1]	0.29		0.36		
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.29, 0.09)		-0.10 (-0.31, 0.11)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.02 (0.68, 1.53)		1.20 (0.95, 1.53)		
p-value [2]	0.93		0.13		
Adjusted interaction test for Treatment*Gender [3]					0.54
Subjects not Transfusion Free at Baseline, n	38	31	18	13	
New Any Type Transfusion Free Rate by Week 24					
Responder, n/N(%)	7/38 (18.4%)	2/31 (6.5%)	5/18 (27.8%)	3/13 (23.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-atf-by24-db-gba.sas V.03.05 Output file: t-sg-atf-by24-db-gba-sex.pdf 29AUG2023: 9:00

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Table 2.4110: Analysis of Rate of Any Type Transfusion Free Response by Week 24 by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Any Type Transfusion Free Rate by Week 24 in DB Phase					
Responder, n(%)	28 (59.6%)	23 (53.5%)	14 (35.9%)	32 (62.7%)	
Unadjusted Inverse Relative Risk (95% CI)	0.90 (0.62, 1.29)		1.75 (1.09, 2.80)		
p-value [1]	0.56		0.020		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.022
Unadjusted Inverse Odds Ratio (95% CI)	0.78 (0.34, 1.80)		3.01 (1.26, 7.15)		
p-value [1]	0.56		0.013		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.14, 0.27)		-0.27 (-0.47, -0.07)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.76 (0.58, 0.98)		1.58 (1.02, 2.45)		
p-value [2]	0.037		0.041		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.011
Subjects not Transfusion Free at Baseline, n	26	21	30	23	
New Any Type Transfusion Free Rate by Week 24					
Responder, n/N(%)	7/26 (26.9%)	1/21 (4.8%)	5/30 (16.7%)	4/23 (17.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-atf-by24-db-gba.sas V.03.05 Output file: t-sg-atf-by24-db-gba-spv.pdf 29AUG2023: 9:00

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Table 2.4109: Analysis of Rate of Any Type Transfusion Free Response by Week 24 by Baseline TSS
Double-blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Any Type Transfusion Free Rate by Week 24 in DB Phase					
Responder, n(%)	20 (45.5%)	32 (58.2%)	22 (53.7%)	23 (60.5%)	
Unadjusted Inverse Relative Risk (95% CI)	1.28 (0.86, 1.90)		1.13 (0.77, 1.65)		
p-value [1]	0.22		0.54		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.65
Unadjusted Inverse Odds Ratio (95% CI)	1.67 (0.75, 3.71)		1.32 (0.54, 3.24)		
p-value [1]	0.21		0.54		
Unadjusted Absolute Risk Difference (95% CI)	-0.13 (-0.32, 0.07)		-0.07 (-0.29, 0.15)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.10 (0.78, 1.55)		1.05 (0.76, 1.45)		
p-value [2]	0.59		0.75		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.95
Subjects not Transfusion Free at Baseline, n	31	26	24	17	
New Any Type Transfusion Free Rate by Week 24					
Responder, n/N(%)	7/31 (22.6%)	3/26 (11.5%)	5/24 (20.8%)	2/17 (11.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-atf-by24-db-gba.sas V.03.05 Output file: t-sg-atf-by24-db-gba-tss.pdf 29AUG2023: 9:00

Table 2.2002: RBC Transfusion-free Rate at Week 24 by Age
Double-blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
RBC Transfusion Free Rate at Week 24					
Responder, n(%)	13 (54.2%)	17 (47.2%)	31 (50.0%)	14 (24.1%)	
95% Exact CI	0.3282, 0.7445	0.3041, 0.6451	0.3702, 0.6298	0.1387, 0.3717	
Proportion Difference - Stratified CMH Method (95% CI)	0.03 (-0.27, 0.34)		0.30 (0.12, 0.47)		
p-value	0.83		<0.001		
Proportion Difference - Unstratified CMH Method (95% CI)	0.07 (-0.19, 0.33)		0.26 (0.09, 0.43)		
p-value	0.60		0.003		
Proportion Difference - Unstratified Exact Method (95% CI)	0.07 (-0.19, 0.33)		0.26 (0.08, 0.43)		
p-value	0.79		0.005		
Unadjusted Inverse Relative Risk (95% CI)	0.87 (0.53, 1.44)		0.48 (0.29, 0.81)		
p-value [1]	0.59		0.006		
Unadjusted interaction test for Treatment*Age Group [3]					0.10
Unadjusted Inverse Odds Ratio (95% CI)	0.76 (0.27, 2.13)		0.32 (0.15, 0.69)		
p-value [1]	0.60		0.004		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.19, 0.33)		0.26 (0.09, 0.42)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.94 (0.55, 1.59)		0.44 (0.26, 0.73)		
p-value [2]	0.81		0.002		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-tfr-at24-db-gba.sas V.03.05 Output file: t-sg-rbc-tfr-at24-db-gba-age.pdf 29AUG2023: 9:01

Table 2.2002: RBC Transfusion-free Rate at Week 24 by Age
Double-blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Adjusted interaction test for Treatment*Age Group [3]					0.077
Non-responder, n(%)	11 (45.8%)	19 (52.8%)	31 (50.0%)	44 (75.9%)	
RBC Transfusion within 12 weeks prior to Week 24	7 (29.2%)	16 (44.4%)	19 (30.6%)	39 (67.2%)	
Discontinued prior to week 24	4 (16.7%)	3 (8.3%)	12 (19.4%)	5 (8.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-tfr-at24-db-gba.sas V.03.05 Output file: t-sg-rbc-tfr-at24-db-gba-age.pdf 29AUG2023: 9:01

Table 2.2007: RBC Transfusion-free Rate at Week 24 by Baseline Hemoglobin Level
Double-blind Phase
ITT-Anemic Analysis Set

	HGB <8g/dL		HGB >=8g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
RBC Transfusion Free Rate at Week 24					
Responder, n(%)	11 (39.3%)	4 (19.0%)	33 (56.9%)	27 (37.0%)	
95% Exact CI	0.2150, 0.5942	0.0545, 0.4191	0.4323, 0.6984	0.2597, 0.4909	
Proportion Difference - Stratified CMH Method (95% CI)	0.20 (-0.07, 0.47)		0.22 (0.04, 0.39)		
p-value	0.14		0.015		
Proportion Difference - Unstratified CMH Method (95% CI)	0.20 (-0.05, 0.46)		0.20 (0.03, 0.37)		
p-value	0.12		0.022		
Proportion Difference - Unstratified Exact Method (95% CI)	0.20 (-0.09, 0.47)		0.20 (0.03, 0.36)		
p-value	0.21		0.034		
Unadjusted Inverse Relative Risk (95% CI)	0.48 (0.18, 1.31)		0.65 (0.45, 0.94)		
p-value [1]	0.15		0.024		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.57
Unadjusted Inverse Odds Ratio (95% CI)	0.36 (0.10, 1.37)		0.44 (0.22, 0.90)		
p-value [1]	0.14		0.024		
Unadjusted Absolute Risk Difference (95% CI)	0.20 (-0.04, 0.45)		0.20 (0.03, 0.37)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.49 (0.18, 1.31)		0.63 (0.43, 0.91)		
p-value [2]	0.15		0.013		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.2007: RBC Transfusion-free Rate at Week 24 by Baseline Hemoglobin Level
Double-blind Phase
ITT-Anemic Analysis Set

	HGB <8g/dL		HGB >=8g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.63
Non-responder, n(%)	17 (60.7%)	17 (81.0%)	25 (43.1%)	46 (63.0%)	
RBC Transfusion within 12 weeks prior to Week 24	11 (39.3%)	13 (61.9%)	15 (25.9%)	42 (57.5%)	
Discontinued prior to week 24	6 (21.4%)	4 (19.0%)	10 (17.2%)	4 (5.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-tfr-at24-db-gba.sas V.03.05 Output file: t-sg-rbc-tfr-at24-db-gba-hgb.pdf 29AUG2023: 9:01

Table 2.2006: RBC Transfusion-free Rate at Week 24 by Baseline IPSS Two-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
RBC Transfusion Free Rate at Week 24					
Responder, n(%)	16 (57.1%)	10 (41.7%)	28 (48.3%)	21 (30.0%)	
95% Exact CI	0.3718, 0.7554	0.2211, 0.6336	0.3495, 0.6178	0.1962, 0.4213	
Proportion Difference - Stratified CMH Method (95% CI)	0.20 (-0.11, 0.50)		0.20 (0.03, 0.37)		
p-value	0.20		0.019		
Proportion Difference - Unstratified CMH Method (95% CI)	0.15 (-0.12, 0.43)		0.18 (0.01, 0.35)		
p-value	0.27		0.034		
Proportion Difference - Unstratified Exact Method (95% CI)	0.15 (-0.12, 0.42)		0.18 (0.01, 0.35)		
p-value	0.40		0.045		
Unadjusted Inverse Relative Risk (95% CI)	0.73 (0.41, 1.29)		0.62 (0.40, 0.97)		
p-value [1]	0.28		0.037		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.67
Unadjusted Inverse Odds Ratio (95% CI)	0.54 (0.18, 1.62)		0.46 (0.22, 0.95)		
p-value [1]	0.27		0.036		
Unadjusted Absolute Risk Difference (95% CI)	0.15 (-0.11, 0.42)		0.18 (0.02, 0.35)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.67 (0.40, 1.13)		0.58 (0.37, 0.91)		
p-value [2]	0.13		0.018		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-tfr-at24-db-gba.sas V.03.05 Output file: t-sg-rbc-tfr-at24-db-gba-ip2.pdf 29AUG2023: 9:01

Table 2.2006: RBC Transfusion-free Rate at Week 24 by Baseline IPSS Two-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.75
Non-responder, n(%)	12 (42.9%)	14 (58.3%)	30 (51.7%)	49 (70.0%)	
RBC Transfusion within 12 weeks prior to Week 24	8 (28.6%)	12 (50.0%)	18 (31.0%)	43 (61.4%)	
Discontinued prior to week 24	4 (14.3%)	2 (8.3%)	12 (20.7%)	6 (8.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

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Table 2.2005: RBC Transfusion-free Rate at Week 24 by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
RBC Transfusion Free Rate at Week 24				
Responder, n(%)	2 (100.0%)	2 (50.0%)	14 (53.8%)	8 (40.0%)
95% Exact CI	0.1581, 1.0000	0.0676, 0.9324	0.3337, 0.7341	0.1912, 0.6395
Proportion Difference - Stratified CMH Method (95% CI)	0.00 (-1.03, 1.03)		0.15 (-0.15, 0.46)	
p-value	1.00		0.33	
Proportion Difference - Unstratified CMH Method (95% CI)	0.50 (-0.42, 1.42)		0.14 (-0.16, 0.43)	
p-value	0.29		0.36	
Proportion Difference - Unstratified Exact Method (95% CI)	0.50 (-0.45, 0.99)		0.14 (-0.16, 0.42)	
p-value	0.47		0.39	
Unadjusted Inverse Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.2005: RBC Transfusion-free Rate at Week 24 by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=58)	High Risk RUX (N=70)	p-value
RBC Transfusion Free Rate at Week 24			
Responder, n(%)	28 (48.3%)	21 (30.0%)	
95% Exact CI	0.3495, 0.6178	0.1962, 0.4213	
Proportion Difference - Stratified CMH Method (95% CI)	0.20 (0.03, 0.37)		
p-value	0.019		
Proportion Difference - Unstratified CMH Method (95% CI)	0.18 (0.01, 0.35)		
p-value	0.034		
Proportion Difference - Unstratified Exact Method (95% CI)	0.18 (0.01, 0.35)		
p-value	0.045		
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.2005: RBC Transfusion-free Rate at Week 24 by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Non-responder, n(%)	0	2 (50.0%)	12 (46.2%)	12 (60.0%)
RBC Transfusion within 12 weeks prior to Week 24	0	2 (50.0%)	8 (30.8%)	10 (50.0%)
Discontinued prior to week 24	0	0	4 (15.4%)	2 (10.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.2005: RBC Transfusion-free Rate at Week 24 by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	High Risk		
(Continued)	MMB (N=58)	RUX (N=70)	p-value
Non-responder, n(%)	30 (51.7%)	49 (70.0%)	
RBC Transfusion within 12 weeks prior to Week 24	18 (31.0%)	43 (61.4%)	
Discontinued prior to week 24	12 (20.7%)	6 (8.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.2008: RBC Transfusion-free Rate at Week 24 by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
RBC Transfusion Free Rate at Week 24				
Responder, n(%)	33 (55.9%)	23 (42.6%)	5 (31.3%)	7 (25.0%)
95% Exact CI	0.4240, 0.6884	0.2923, 0.5679	0.1102, 0.5866	0.1069, 0.4487
Proportion Difference - Stratified CMH Method (95% CI)	0.14 (-0.05, 0.33)		0.07 (-0.22, 0.36)	
p-value	0.14		0.63	
Proportion Difference - Unstratified CMH Method (95% CI)	0.13 (-0.05, 0.32)		0.06 (-0.23, 0.35)	
p-value	0.16		0.67	
Proportion Difference - Unstratified Exact Method (95% CI)	0.13 (-0.05, 0.31)		0.06 (-0.25, 0.36)	
p-value	0.19		0.73	
Unadjusted Inverse Relative Risk (95% CI)	0.76 (0.52, 1.12)		0.80 (0.30, 2.11)	
p-value [1]	0.16		0.65	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.58 (0.28, 1.23)		0.73 (0.19, 2.86)	
p-value [1]	0.16		0.65	
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.05, 0.32)		0.06 (-0.22, 0.34)	
Adjusted Inverse Relative Risk (95% CI) [2]	0.75 (0.51, 1.10)		NE	
p-value [2]	0.14		NE	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-tfr-at24-db-gba.sas V.03.05 Output file: t-sg-rbc-tfr-at24-db-gba-mf.pdf 29AUG2023: 9:01

Table 2.2008: RBC Transfusion-free Rate at Week 24 by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=11)	Post-PV Myelofibrosis RUX (N=12)	p-value
RBC Transfusion Free Rate at Week 24			
Responder, n(%)	6 (54.5%)	1 (8.3%)	
95% Exact CI	0.2338, 0.8325	0.0021, 0.3848	
Proportion Difference - Stratified CMH Method (95% CI)	0.55 (0.14, 0.96)		
p-value	0.008		
Proportion Difference - Unstratified CMH Method (95% CI)	0.46 (0.10, 0.82)		
p-value	0.012		
Proportion Difference - Unstratified Exact Method (95% CI)	0.46 (0.03, 0.77)		
p-value	0.027		
Unadjusted Inverse Relative Risk (95% CI)	0.15 (0.02, 1.08)		
p-value [1]	0.059		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.11
Unadjusted Inverse Odds Ratio (95% CI)	0.08 (0.01, 0.81)		
p-value [1]	0.033		
Unadjusted Absolute Risk Difference (95% CI)	0.46 (0.13, 0.80)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.2008: RBC Transfusion-free Rate at Week 24 by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-responder, n(%)	26 (44.1%)	31 (57.4%)	11 (68.8%)	21 (75.0%)
RBC Transfusion within 12 weeks prior to Week 24	16 (27.1%)	27 (50.0%)	8 (50.0%)	19 (67.9%)
Discontinued prior to week 24	10 (16.9%)	4 (7.4%)	3 (18.8%)	2 (7.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.2008: RBC Transfusion-free Rate at Week 24 by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
(Continued)	MMB (N=11)	RUX (N=12)	p-value
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.049
Non-responder, n(%)	5 (45.5%)	11 (91.7%)	
RBC Transfusion within 12 weeks prior to Week 24	2 (18.2%)	9 (75.0%)	
Discontinued prior to week 24	3 (27.3%)	2 (16.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.2004: RBC Transfusion-free Rate at Week 24 by Region
Double-blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
RBC Transfusion Free Rate at Week 24					
Responder, n(%)	22 (41.5%)	15 (29.4%)	22 (66.7%)	16 (37.2%)	
95% Exact CI	0.2814, 0.5587	0.1749, 0.4383	0.4817, 0.8204	0.2298, 0.5327	
Proportion Difference - Stratified CMH Method (95% CI)	0.17 (-0.03, 0.36)		0.30 (0.07, 0.53)		
p-value	0.090		0.010		
Proportion Difference - Unstratified CMH Method (95% CI)	0.12 (-0.06, 0.31)		0.29 (0.07, 0.51)		
p-value	0.20		0.009		
Proportion Difference - Unstratified Exact Method (95% CI)	0.12 (-0.07, 0.31)		0.29 (0.07, 0.50)		
p-value	0.22		0.020		
Unadjusted Inverse Relative Risk (95% CI)	0.71 (0.42, 1.21)		0.56 (0.35, 0.88)		
p-value [1]	0.20		0.012		
Unadjusted interaction test for Treatment*Region [3]					0.51
Unadjusted Inverse Odds Ratio (95% CI)	0.59 (0.26, 1.32)		0.30 (0.11, 0.77)		
p-value [1]	0.20		0.012		
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.06, 0.30)		0.29 (0.08, 0.51)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.62 (0.36, 1.04)		NE		
p-value [2]	0.071		NE		
Adjusted interaction test for Treatment*Region [3]					0.61

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-tfr-at24-db-gba.sas V.03.05 Output file: t-sg-rbc-tfr-at24-db-gba-reg.pdf 29AUG2023: 9:01

Table 2.2004: RBC Transfusion-free Rate at Week 24 by Region
Double-blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Non-responder, n(%)	31 (58.5%)	36 (70.6%)	11 (33.3%)	27 (62.8%)	
RBC Transfusion within 12 weeks prior to Week 24	21 (39.6%)	31 (60.8%)	5 (15.2%)	24 (55.8%)	
Discontinued prior to week 24	10 (18.9%)	5 (9.8%)	6 (18.2%)	3 (7.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-tfr-at24-db-gba.sas V.03.05 Output file: t-sg-rbc-tfr-at24-db-gba-reg.pdf 29AUG2023: 9:01

Table 2.2003: RBC Transfusion-free Rate at Week 24 by Gender
Double-blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
RBC Transfusion Free Rate at Week 24					
Responder, n(%)	23 (46.0%)	18 (32.1%)	21 (58.3%)	13 (34.2%)	
95% Exact CI	0.3181, 0.6068	0.2029, 0.4596	0.4076, 0.7449	0.1963, 0.5135	
Proportion Difference - Stratified CMH Method (95% CI)	0.20 (0.01, 0.39)		0.22 (-0.02, 0.46)		
p-value	0.040		0.078		
Proportion Difference - Unstratified CMH Method (95% CI)	0.14 (-0.05, 0.33)		0.24 (0.02, 0.47)		
p-value	0.15		0.035		
Proportion Difference - Unstratified Exact Method (95% CI)	0.14 (-0.05, 0.32)		0.24 (0.01, 0.45)		
p-value	0.17		0.061		
Unadjusted Inverse Relative Risk (95% CI)	0.70 (0.43, 1.13)		0.59 (0.35, 0.99)		
p-value [1]	0.15		0.044		
Unadjusted interaction test for Treatment*Gender [3]					0.63
Unadjusted Inverse Odds Ratio (95% CI)	0.56 (0.25, 1.23)		0.37 (0.14, 0.95)		
p-value [1]	0.15		0.039		
Unadjusted Absolute Risk Difference (95% CI)	0.14 (-0.05, 0.32)		0.24 (0.02, 0.46)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.60 (0.37, 0.96)		0.62 (0.36, 1.05)		
p-value [2]	0.034		0.077		
Adjusted interaction test for Treatment*Gender [3]					0.97

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.2003: RBC Transfusion-free Rate at Week 24 by Gender
Double-blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Non-responder, n(%)	27 (54.0%)	38 (67.9%)	15 (41.7%)	25 (65.8%)	
RBC Transfusion within 12 weeks prior to Week 24	21 (42.0%)	32 (57.1%)	5 (13.9%)	23 (60.5%)	
Discontinued prior to week 24	6 (12.0%)	6 (10.7%)	10 (27.8%)	2 (5.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.2010: RBC Transfusion-free Rate at Week 24 by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
RBC Transfusion Free Rate at Week 24					
Responder, n(%)	26 (55.3%)	10 (23.3%)	18 (46.2%)	21 (41.2%)	
95% Exact CI	0.4012, 0.6983	0.1176, 0.3863	0.3009, 0.6282	0.2758, 0.5583	
Proportion Difference - Stratified CMH Method (95% CI)	0.33 (0.12, 0.54)		0.10 (-0.11, 0.32)		
p-value	0.002		0.36		
Proportion Difference - Unstratified CMH Method (95% CI)	0.32 (0.13, 0.51)		0.05 (-0.16, 0.26)		
p-value	0.001		0.64		
Proportion Difference - Unstratified Exact Method (95% CI)	0.32 (0.12, 0.51)		0.05 (-0.16, 0.26)		
p-value	0.003		0.67		
Unadjusted Inverse Relative Risk (95% CI)	0.42 (0.23, 0.77)		0.89 (0.56, 1.43)		
p-value [1]	0.005		0.64		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.044
Unadjusted Inverse Odds Ratio (95% CI)	0.24 (0.10, 0.61)		0.82 (0.35, 1.89)		
p-value [1]	0.002		0.64		
Unadjusted Absolute Risk Difference (95% CI)	0.32 (0.13, 0.51)		0.05 (-0.16, 0.26)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.79 (0.50, 1.26)		
p-value [2]	NE		0.32		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-tfr-at24-db-gba.sas V.03.05 Output file: t-sg-rbc-tfr-at24-db-gba-spv.pdf 29AUG2023: 9:02

Table 2.2010: RBC Transfusion-free Rate at Week 24 by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.089
Non-responder, n(%)	21 (44.7%)	33 (76.7%)	21 (53.8%)	30 (58.8%)	
RBC Transfusion within 12 weeks prior to Week 24	14 (29.8%)	29 (67.4%)	12 (30.8%)	26 (51.0%)	
Discontinued prior to week 24	7 (14.9%)	4 (9.3%)	9 (23.1%)	4 (7.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-tfr-at24-db-gba.sas V.03.05 Output file: t-sg-rbc-tfr-at24-db-gba-spv.pdf 29AUG2023: 9:02

Table 2.2009: RBC Transfusion-free Rate at Week 24 by Baseline TSS
Double-blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
RBC Transfusion Free Rate at Week 24					
Responder, n(%)	25 (56.8%)	19 (34.5%)	18 (43.9%)	12 (31.6%)	
95% Exact CI	0.4103, 0.7165	0.2224, 0.4858	0.2847, 0.6025	0.1750, 0.4865	
Proportion Difference - Stratified CMH Method (95% CI)	0.25 (0.05, 0.45)		0.14 (-0.08, 0.36)		
p-value	0.013		0.20		
Proportion Difference - Unstratified CMH Method (95% CI)	0.22 (0.03, 0.42)		0.12 (-0.09, 0.34)		
p-value	0.025		0.26		
Proportion Difference - Unstratified Exact Method (95% CI)	0.22 (0.02, 0.41)		0.12 (-0.10, 0.34)		
p-value	0.041		0.35		
Unadjusted Inverse Relative Risk (95% CI)	0.61 (0.39, 0.95)		0.72 (0.40, 1.29)		
p-value [1]	0.029		0.27		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.66
Unadjusted Inverse Odds Ratio (95% CI)	0.40 (0.18, 0.91)		0.59 (0.23, 1.48)		
p-value [1]	0.028		0.26		
Unadjusted Absolute Risk Difference (95% CI)	0.22 (0.03, 0.42)		0.12 (-0.09, 0.34)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.69 (0.40, 1.19)		
p-value [2]	NE		0.18		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-tfr-at24-db-gba.sas V.03.05 Output file: t-sg-rbc-tfr-at24-db-gba-tss.pdf 29AUG2023: 9:02

Table 2.2009: RBC Transfusion-free Rate at Week 24 by Baseline TSS
Double-blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.53
Non-responder, n(%)	19 (43.2%)	36 (65.5%)	23 (56.1%)	26 (68.4%)	
RBC Transfusion within 12 weeks prior to Week 24	16 (36.4%)	32 (58.2%)	10 (24.4%)	22 (57.9%)	
Discontinued prior to week 24	3 (6.8%)	4 (7.3%)	13 (31.7%)	4 (10.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-tfr-at24-db-gba.sas V.03.05 Output file: t-sg-rbc-tfr-at24-db-gba-tss.pdf 29AUG2023: 9:02

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Table 2.2402: Analysis of Rate of RBC Transfusion Free Response by Week 24 by Age
Double-blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
RBC Transfusion Free Rate by Week 24 in DB Phase					
Responder, n(%)	17 (70.8%)	27 (75.0%)	37 (59.7%)	33 (56.9%)	
Unadjusted Inverse Relative Risk (95% CI)	1.06 (0.77, 1.46)		0.95 (0.70, 1.29)		
p-value [1]	0.73		0.76		
Unadjusted interaction test for Treatment*Age Group [3]					0.64
Unadjusted Inverse Odds Ratio (95% CI)	1.24 (0.39, 3.94)		0.89 (0.43, 1.84)		
p-value [1]	0.72		0.76		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.27, 0.19)		0.03 (-0.15, 0.20)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.09 (0.80, 1.50)		0.81 (0.63, 1.06)		
p-value [2]	0.59		0.12		
Adjusted interaction test for Treatment*Age Group [3]					0.28
Subjects not Transfusion Free at Baseline, n	13	13	43	31	
New RBC Transfusion Free Rate by Week 24					
Responder, n/N(%)	6/13 (46.2%)	4/13 (30.8%)	18/43 (41.9%)	6/31 (19.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-tf-by24.sas V.03.05 Output file: t-sg-tf-rbc24-age.pdf 29AUG2023: 9:34

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Table 2.2407: Analysis of Rate of RBC Transfusion Free Response by Week 24 by Baseline Hemoglobin Level
Double-blind Phase
ITT-Anemic Analysis Set

	HGB <8g/dL		HGB >=8g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
RBC Transfusion Free Rate by Week 24 in DB Phase					
Responder, n(%)	13 (46.4%)	8 (38.1%)	41 (70.7%)	52 (71.2%)	
Unadjusted Inverse Relative Risk (95% CI)	0.82 (0.42, 1.61)		1.01 (0.81, 1.26)		
p-value [1]	0.57		0.95		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.56
Unadjusted Inverse Odds Ratio (95% CI)	0.71 (0.22, 2.25)		1.03 (0.48, 2.19)		
p-value [1]	0.56		0.95		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.19, 0.36)		-0.01 (-0.16, 0.15)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.82 (0.42, 1.60)		0.97 (0.80, 1.18)		
p-value [2]	0.55		0.76		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.63
Subjects not Transfusion Free at Baseline, n	25	16	31	28	
New RBC Transfusion Free Rate by Week 24					
Responder, n/N(%)	10/25 (40.0%)	3/16 (18.8%)	14/31 (45.2%)	7/28 (25.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-tf-by24.sas V.03.05 Output file: t-sg-tf-rbc24-hgb.pdf 29AUG2023: 9:35

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Table 2.2406: Analysis of Rate of RBC Transfusion Free Response by Week 24 by Baseline IPSS Two-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
RBC Transfusion Free Rate by Week 24 in DB Phase					
Responder, n(%)	19 (67.9%)	17 (70.8%)	35 (60.3%)	43 (61.4%)	
Unadjusted Inverse Relative Risk (95% CI)	1.04 (0.73, 1.50)		1.02 (0.77, 1.35)		
p-value [1]	0.82		0.90		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.91
Unadjusted Inverse Odds Ratio (95% CI)	1.15 (0.35, 3.76)		1.05 (0.51, 2.14)		
p-value [1]	0.82		0.90		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.28, 0.22)		-0.01 (-0.18, 0.16)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.96 (0.70, 1.32)		0.94 (0.73, 1.21)		
p-value [2]	0.80		0.63		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.88
Subjects not Transfusion Free at Baseline, n	15	7	41	37	
New RBC Transfusion Free Rate by Week 24					
Responder, n/N(%)	6/15 (40.0%)	0	18/41 (43.9%)	10/37 (27.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-tf-by24.sas V.03.05 Output file: t-sg-tf-rbc24-ip2.pdf 29AUG2023: 9:35

Table 2.2405: Analysis of Rate of RBC Transfusion Free Response by Week 24 by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
RBC Transfusion Free Rate by Week 24 in DB Phase				
Responder, n(%)	2 (100.0%)	2 (50.0%)	17 (65.4%)	15 (75.0%)
Unadjusted Inverse Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Subjects not Transfusion Free at Baseline, n	0	2	15	5
New RBC Transfusion Free Rate by Week 24				
Responder, n/N(%)	0	0	6/15 (40.0%)	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-tf-by24.sas V.03.05 Output file: t-sg-tf-rbc24-ip3.pdf 29AUG2023: 9:34

Table 2.2405: Analysis of Rate of RBC Transfusion Free Response by Week 24 by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=58)	High Risk RUX (N=70)	p-value
RBC Transfusion Free Rate by Week 24 in DB Phase			
Responder, n(%)	35 (60.3%)	43 (61.4%)	
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Subjects not Transfusion Free at Baseline, n	41	37	
New RBC Transfusion Free Rate by Week 24			
Responder, n/N(%)	18/41 (43.9%)	10/37 (27.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-tf-by24.sas V.03.05 Output file: t-sg-tf-rbc24-ip3.pdf 29AUG2023: 9:34

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Table 2.2408: Analysis of Rate of RBC Transfusion Free Response by Week 24 by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
RBC Transfusion Free Rate by Week 24 in DB Phase				
Responder, n(%)	39 (66.1%)	36 (66.7%)	9 (56.3%)	19 (67.9%)
Unadjusted Inverse Relative Risk (95% CI)	1.01 (0.78, 1.31)		1.21 (0.73, 1.99)	
p-value [1]	0.95		0.46	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	1.03 (0.47, 2.24)		1.64 (0.46, 5.83)	
p-value [1]	0.95		0.44	
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.18, 0.17)		-0.12 (-0.41, 0.18)	
Adjusted Inverse Relative Risk (95% CI) [2]	0.98 (0.77, 1.24)		NE	
p-value [2]	0.86		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Subjects not Transfusion Free at Baseline, n	38	27	10	10
New RBC Transfusion Free Rate by Week 24				
Responder, n/N(%)	18/38 (47.4%)	9/27 (33.3%)	3/10 (30.0%)	1/10 (10.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-tf-by24.sas V.03.05 Output file: t-sg-tf-rbc24-mf.pdf 29AUG2023: 9:35

Table 2.2408: Analysis of Rate of RBC Transfusion Free Response by Week 24 by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=11)	Post-PV Myelofibrosis RUX (N=12)	p-value
RBC Transfusion Free Rate by Week 24 in DB Phase			
Responder, n(%)	6 (54.5%)	5 (41.7%)	
Unadjusted Inverse Relative Risk (95% CI)	0.76 (0.32, 1.80)		
p-value [1]	0.54		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.64
Unadjusted Inverse Odds Ratio (95% CI)	0.60 (0.11, 3.10)		
p-value [1]	0.54		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.28, 0.53)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.37
Subjects not Transfusion Free at Baseline, n	8	7	
New RBC Transfusion Free Rate by Week 24			
Responder, n/N(%)	3/8 (37.5%)	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-tf-by24.sas V.03.05 Output file: t-sg-tf-rbc24-mf.pdf 29AUG2023: 9:35

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Table 2.2404: Analysis of Rate of RBC Transfusion Free Response by Week 24 by Region
Double-blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
RBC Transfusion Free Rate by Week 24 in DB Phase					
Responder, n(%)	28 (52.8%)	28 (54.9%)	26 (78.8%)	32 (74.4%)	
Unadjusted Inverse Relative Risk (95% CI)	1.04 (0.73, 1.48)		0.94 (0.74, 1.21)		
p-value [1]	0.83		0.65		
Unadjusted interaction test for Treatment*Region [3]					0.67
Unadjusted Inverse Odds Ratio (95% CI)	1.09 (0.50, 2.35)		0.78 (0.27, 2.31)		
p-value [1]	0.83		0.66		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.21, 0.17)		0.04 (-0.15, 0.23)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.87 (0.64, 1.17)		0.95 (0.75, 1.21)		
p-value [2]	0.35		0.69		
Adjusted interaction test for Treatment*Region [3]					0.80
Subjects not Transfusion Free at Baseline, n	40	27	16	17	
New RBC Transfusion Free Rate by Week 24					
Responder, n/N(%)	15/40 (37.5%)	4/27 (14.8%)	9/16 (56.3%)	6/17 (35.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-tf-by24.sas V.03.05 Output file: t-sg-tf-rbc24-reg.pdf 29AUG2023: 9:34

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Table 2.2403: Analysis of Rate of RBC Transfusion Free Response by Week 24 by Gender
Double-blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
RBC Transfusion Free Rate by Week 24 in DB Phase					
Responder, n(%)	27 (54.0%)	32 (57.1%)	27 (75.0%)	28 (73.7%)	
Unadjusted Inverse Relative Risk (95% CI)	1.06 (0.75, 1.49)		0.98 (0.75, 1.28)		
p-value [1]	0.75		0.90		
Unadjusted interaction test for Treatment*Gender [3]					0.74
Unadjusted Inverse Odds Ratio (95% CI)	1.14 (0.53, 2.45)		0.93 (0.33, 2.65)		
p-value [1]	0.75		0.90		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.22, 0.16)		0.01 (-0.19, 0.21)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.90 (0.65, 1.24)		1.00 (0.79, 1.27)		
p-value [2]	0.51		0.99		
Adjusted interaction test for Treatment*Gender [3]					0.64
Subjects not Transfusion Free at Baseline, n	38	31	18	13	
New RBC Transfusion Free Rate by Week 24					
Responder, n/N(%)	15/38 (39.5%)	7/31 (22.6%)	9/18 (50.0%)	3/13 (23.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-tf-by24.sas V.03.05 Output file: t-sg-tf-rbc24-sex.pdf 29AUG2023: 9:34

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Table 2.2410: Analysis of Rate of RBC Transfusion Free Response by Week 24 by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
RBC Transfusion Free Rate by Week 24 in DB Phase					
Responder, n(%)	33 (70.2%)	25 (58.1%)	21 (53.8%)	35 (68.6%)	
Unadjusted Inverse Relative Risk (95% CI)	0.83 (0.60, 1.13)		1.27 (0.90, 1.80)		
p-value [1]	0.24		0.17		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.064
Unadjusted Inverse Odds Ratio (95% CI)	0.59 (0.25, 1.41)		1.88 (0.79, 4.45)		
p-value [1]	0.23		0.15		
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.08, 0.32)		-0.15 (-0.35, 0.05)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.73 (0.56, 0.95)		1.13 (0.81, 1.56)		
p-value [2]	0.020		0.47		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.065
Subjects not Transfusion Free at Baseline, n	26	21	30	23	
New RBC Transfusion Free Rate by Week 24					
Responder, n/N(%)	12/26 (46.2%)	3/21 (14.3%)	12/30 (40.0%)	7/23 (30.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-tf-by24.sas V.03.05 Output file: t-sg-tf-rbc24-spv.pdf 29AUG2023: 9:35

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Table 2.2409: Analysis of Rate of RBC Transfusion Free Response by Week 24 by Baseline TSS
Double-blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
RBC Transfusion Free Rate by Week 24 in DB Phase					
Responder, n(%)	28 (63.6%)	37 (67.3%)	25 (61.0%)	23 (60.5%)	
Unadjusted Inverse Relative Risk (95% CI)	1.06 (0.79, 1.41)		0.99 (0.70, 1.42)		
p-value [1]	0.71		0.97		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.79
Unadjusted Inverse Odds Ratio (95% CI)	1.17 (0.51, 2.70)		0.98 (0.40, 2.42)		
p-value [1]	0.71		0.97		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.22, 0.15)		0.00 (-0.21, 0.22)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.95 (0.73, 1.24)		0.94 (0.69, 1.28)		
p-value [2]	0.73		0.68		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.95
Subjects not Transfusion Free at Baseline, n	31	26	24	17	
New RBC Transfusion Free Rate by Week 24					
Responder, n/N(%)	15/31 (48.4%)	8/26 (30.8%)	8/24 (33.3%)	2/17 (11.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-tf-by24.sas V.03.05 Output file: t-sg-tf-rbc24-tss.pdf 29AUG2023: 9:35

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Table 2.2401: Analysis of Rate of RBC Transfusion Free Response by Week 24
Double-blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
RBC Transfusion Free Rate by Week 24 in DB Phase			
Responder, n(%)	54 (62.8%)	60 (63.8%)	114 (63.3%)
Unadjusted Inverse Relative Risk (95% CI)	1.02 (0.81, 1.27)		
p-value [1]	0.89		
Unadjusted Inverse Odds Ratio (95% CI)	1.05 (0.57, 1.92)		
p-value [1]	0.89		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.15, 0.13)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.94 (0.77, 1.15)		
p-value [2]	0.55		
Subjects not Transfusion Free at Baseline, n	56	44	100
New RBC Transfusion Free Rate by Week 24			
Responder, n/N(%)	24/56 (42.9%)	10/44 (22.7%)	34/100 (34.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and RUX group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization, excluding RBC transfusion associated with clinically overt bleeding. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

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Table 2.4302: Analysis of Time to Any Type Transfusion Free Response by Age
Double-blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Subjects with Event					
Any Type Transfusion Free Response, n(%)	18 (75.0%)	19 (52.8%)	34 (54.8%)	20 (34.5%)	
Censor					
Subjects Censored, n(%)	6 (25.0%)	17 (47.2%)	28 (45.2%)	38 (65.5%)	
Kaplan-Meier Estimate of Time to Any Type Transfusion Free Response (Weeks)					
25-percentile (95% CI)	12.14 (NE, NE)	12.14 (12.14, 18.00)	12.14 (NE, NE)	19.43 (12.14, NE)	
Median (95% CI)	12.14 (12.14, 14.14)	22.29 (12.14, NE)	14.00 (12.14, 23.14)	NE (NE, NE)	
75-percentile (95% CI)	24.14 (12.14, NE)	NE (NE, NE)	NE (23.14, NE)	NE (NE, NE)	
Min, Max	5.29, 24.57	11.14, 24.57	1.29, 24.57	12.00, 27.00	
Stratified Log-Rank Test p-value	0.10		< 0.001		
Adjusted Inverse Hazard Ratio (95% CI)	0.48 (0.24, 0.96)		0.30 (0.17, 0.55)		
Unstratified Log-Rank Test p-value	0.069		0.002		
Unadjusted Inverse Hazard Ratio (95% CI)	0.55 (0.29, 1.06)		0.42 (0.24, 0.73)		
P-value for interaction test					0.34

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusions of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-any-tfr-sub.sas V.03.05 Output file: t-tte-any-tfr-age.pdf 24AUG2023:12:44

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Table 2.4304: Analysis of Time to Any Type Transfusion Free Response by Region
Double-blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Subjects with Event					
Any Type Transfusion Free Response, n(%)	28 (52.8%)	18 (35.3%)	24 (72.7%)	21 (48.8%)	
Censor					
Subjects Censored, n(%)	25 (47.2%)	33 (64.7%)	9 (27.3%)	22 (51.2%)	
Kaplan-Meier Estimate of Time to Any Type Transfusion Free Response (Weeks)					
25-percentile (95% CI)	12.14 (NE, NE)	17.00 (12.14, 22.29)	12.14 (NE, NE)	12.14 (12.14, 20.43)	
Median (95% CI)	14.00 (12.14, NE)	NE (20.71, NE)	12.14 (12.14, 21.86)	NE (20.00, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	23.43 (12.14, NE)	NE (NE, NE)	
Min, Max	1.29, 24.57	11.14, 27.00	2.71, 24.57	12.14, 25.14	
Stratified Log-Rank Test p-value	0.003		0.002		
Adjusted Inverse Hazard Ratio (95% CI)	0.36 (0.20, 0.68)		0.34 (0.18, 0.62)		
Unstratified Log-Rank Test p-value	0.021		0.004		
Unadjusted Inverse Hazard Ratio (95% CI)	0.50 (0.28, 0.91)		0.42 (0.23, 0.76)		
P-value for interaction test					0.88

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusions of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-any-tfr-sub.sas V.03.05 Output file: t-tte-any-tfr-geo.pdf 24AUG2023:12:44

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Table 2.4307: Analysis of Time to Any Type Transfusion Free Response by Baseline Hemoglobin Level

Double-blind Phase

ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Subjects with Event					
Any Type Transfusion Free Response, n(%)	12 (42.9%)	5 (23.8%)	40 (69.0%)	34 (46.6%)	
Censor					
Subjects Censored, n(%)	16 (57.1%)	16 (76.2%)	18 (31.0%)	39 (53.4%)	
Kaplan-Meier Estimate of Time to Any Type Transfusion Free Response (Weeks)					
25-percentile (95% CI)	12.14 (12.14, 23.14)	20.71 (12.14, NE)	12.14 (NE, NE)	12.14 (12.14, 20.00)	
Median (95% CI)	24.14 (12.71, NE)	NE (20.71, NE)	12.14 (12.14, 12.43)	NE (20.29, NE)	
75-percentile (95% CI)	NE (24.14, NE)	NE (NE, NE)	22.86 (12.29, NE)	NE (NE, NE)	
Min, Max	1.29, 24.43	11.14, 24.57	1.29, 24.57	12.14, 27.00	
Stratified Log-Rank Test p-value	0.13		< 0.001		
Adjusted Inverse Hazard Ratio (95% CI)	0.46 (0.16, 1.32)		0.37 (0.23, 0.59)		
Unstratified Log-Rank Test p-value	0.13		< 0.001		
Unadjusted Inverse Hazard Ratio (95% CI)	0.46 (0.16, 1.32)		0.43 (0.27, 0.69)		
P-value for interaction test					0.69

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusions of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019

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Table 2.4306: Analysis of Time to Any Type Transfusion Free Response by Baseline IPSS Two-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Subjects with Event					
Any Type Transfusion Free Response, n(%)	19 (67.9%)	10 (41.7%)	33 (56.9%)	29 (41.4%)	
Censor					
Subjects Censored, n(%)	9 (32.1%)	14 (58.3%)	25 (43.1%)	41 (58.6%)	
Kaplan-Meier Estimate of Time to Any Type Transfusion Free Response (Weeks)					
25-percentile (95% CI)	12.14 (NE, NE)	12.14 (12.14, 22.29)	12.14 (NE, NE)	12.14 (12.14, 20.29)	
Median (95% CI)	12.14 (12.14, 16.29)	NE (12.14, NE)	14.00 (12.14, 23.57)	NE (20.71, NE)	
75-percentile (95% CI)	22.14 (12.14, NE)	NE (NE, NE)	NE (23.43, NE)	NE (NE, NE)	
Min, Max	2.71, 24.57	11.14, 25.14	1.29, 24.57	12.00, 27.00	
Stratified Log-Rank Test p-value	0.004		0.005		
Adjusted Inverse Hazard Ratio (95% CI)	0.28 (0.13, 0.65)		0.42 (0.25, 0.71)		
Unstratified Log-Rank Test p-value	0.017		0.013		
Unadjusted Inverse Hazard Ratio (95% CI)	0.41 (0.19, 0.89)		0.53 (0.32, 0.87)		
P-value for interaction test					0.52

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusions of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-any-tfr-sub.sas V.03.05 Output file: t-tte-any-tfr-ipss2.pdf 24AUG2023:12:44

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Table 2.4305: Analysis of Time to Any Type Transfusion Free Response by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Subjects with Event				
Any Type Transfusion Free Response, n(%)	2 (100.0%)	2 (50.0%)	17 (65.4%)	8 (40.0%)
Censor				
Subjects Censored, n(%)	0	2 (50.0%)	9 (34.6%)	12 (60.0%)
Kaplan-Meier Estimate of Time to Any Type Transfusion Free Response (Weeks)				
25-percentile (95% CI)	12.14 (NE, NE)	17.07 (12.14, NE)	12.14 (NE, NE)	12.14 (12.14, NE)
Median (95% CI)	12.14 (NE, NE)	NE (12.14, NE)	12.14 (12.14, 16.29)	NE (12.14, NE)
75-percentile (95% CI)	12.14 (NE, NE)	NE (12.14, NE)	NE (12.29, NE)	NE (NE, NE)
Min, Max	12.14, 12.14	12.14, 24.14	2.71, 24.57	11.14, 25.14
Stratified Log-Rank Test p-value	NA		NA	
Adjusted Inverse Hazard Ratio (95% CI)	NA		NA	
Unstratified Log-Rank Test p-value	NA		NA	
Unadjusted Inverse Hazard Ratio (95% CI)	NA		NA	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusions of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-any-tfr-sub.sas V.03.05 Output file: t-tte-any-tfr-ipss3.pdf 24AUG2023:12:44

Table 2.4305: Analysis of Time to Any Type Transfusion Free Response by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=58)	High Risk RUX (N=70)	p-value
Subjects with Event			
Any Type Transfusion Free Response, n(%)	33 (56.9%)	29 (41.4%)	
Censor			
Subjects Censored, n(%)	25 (43.1%)	41 (58.6%)	
Kaplan-Meier Estimate of Time to Any Type Transfusion Free Response (Weeks)			
25-percentile (95% CI)	12.14 (NE, NE)	12.14 (12.14, 20.29)	
Median (95% CI)	14.00 (12.14, 23.57)	NE (20.71, NE)	
75-percentile (95% CI)	NE (23.43, NE)	NE (NE, NE)	
Min, Max	1.29, 24.57	12.00, 27.00	
Stratified Log-Rank Test p-value	NA		
Adjusted Inverse Hazard Ratio (95% CI)	NA		
Unstratified Log-Rank Test p-value	NA		
Unadjusted Inverse Hazard Ratio (95% CI)	NA		
P-value for interaction test			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusions of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-any-tfr-sub.sas V.03.05 Output file: t-tte-any-tfr-ipss3.pdf 24AUG2023:12:44

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Table 2.4308: Analysis of Time to Any Type Transfusion Free Response by Baseline MF Disease Status

Double-blind Phase

ITT-Anemic Analysis Set

	Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=16)	RUX (N=28)	MMB (N=11)	RUX (N=12)
Subjects with Event				
Any Type Transfusion Free Response, n(%)	8 (50.0%)	10 (35.7%)	6 (54.5%)	2 (16.7%)
Censor				
Subjects Censored, n(%)	8 (50.0%)	18 (64.3%)	5 (45.5%)	10 (83.3%)
Kaplan-Meier Estimate of Time to Any Type Transfusion Free Response (Weeks)				
25-percentile (95% CI)	12.14 (12.14, 12.29)	12.14 (12.14, NE)	12.14 (NE, NE)	NE (12.14, NE)
Median (95% CI)	12.36 (12.14, NE)	NE (12.14, NE)	12.14 (12.14, NE)	NE (12.14, NE)
75-percentile (95% CI)	NE (12.29, NE)	NE (NE, NE)	NE (12.14, NE)	NE (NE, NE)
Min, Max	1.29, 24.57	11.14, 27.00	1.29, 24.29	12.14, 24.29
Stratified Log-Rank Test p-value	0.077		0.024	
Adjusted Inverse Hazard Ratio (95% CI)	0.37 (0.13, 1.02)		0.12 (0.02, 0.70)	
Unstratified Log-Rank Test p-value	0.26		0.010	
Unadjusted Inverse Hazard Ratio (95% CI)	0.62 (0.24, 1.56)		0.16 (0.03, 0.78)	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusions of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-any-tfr-sub.sas V.03.05 Output file: t-tte-any-tfr-mf.pdf 24AUG2023:12:44

Table 2.4308: Analysis of Time to Any Type Transfusion Free Response by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	Primary Myelofibrosis MMB (N=59)	Primary Myelofibrosis RUX (N=54)	p-value
Subjects with Event			
Any Type Transfusion Free Response, n(%)	38 (64.4%)	27 (50.0%)	
Censor			
Subjects Censored, n(%)	21 (35.6%)	27 (50.0%)	
Kaplan-Meier Estimate of Time to Any Type Transfusion Free Response (Weeks)			
25-percentile (95% CI)	12.14 (NE, NE)	12.14 (12.14, 20.14)	
Median (95% CI)	12.43 (12.14, 22.86)	22.71 (20.00, NE)	
75-percentile (95% CI)	NE (22.86, NE)	NE (NE, NE)	
Min, Max	2.29, 24.57	12.14, 25.14	
Stratified Log-Rank Test p-value	0.028		
Adjusted Inverse Hazard Ratio (95% CI)	0.47 (0.28, 0.78)		
Unstratified Log-Rank Test p-value	0.029		
Unadjusted Inverse Hazard Ratio (95% CI)	0.56 (0.34, 0.92)		
P-value for interaction test			0.14

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusions of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-any-tfr-sub.sas V.03.05 Output file: t-tte-any-tfr-mf.pdf 24AUG2023:12:44

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Table 2.4303: Analysis of Time to Any Type Transfusion Free Response by Gender
Double-blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Subjects with Event					
Any Type Transfusion Free Response, n(%)	28 (56.0%)	22 (39.3%)	24 (66.7%)	17 (44.7%)	
Censor					
Subjects Censored, n(%)	22 (44.0%)	34 (60.7%)	12 (33.3%)	21 (55.3%)	
Kaplan-Meier Estimate of Time to Any Type Transfusion Free Response (Weeks)					
25-percentile (95% CI)	12.14 (NE, NE)	18.00 (12.14, 22.29)	12.14 (NE, NE)	12.14 (12.14, 20.43)	
Median (95% CI)	21.86 (12.14, NE)	NE (20.71, NE)	12.14 (NE, NE)	NE (12.14, NE)	
75-percentile (95% CI)	NE (23.57, NE)	NE (NE, NE)	22.14 (12.14, NE)	NE (NE, NE)	
Min, Max	2.29, 24.57	11.14, 26.71	1.29, 24.57	12.14, 27.00	
Stratified Log-Rank Test p-value	0.015		0.004		
Adjusted Inverse Hazard Ratio (95% CI)	0.45 (0.25, 0.80)		0.32 (0.17, 0.62)		
Unstratified Log-Rank Test p-value	0.049		0.001		
Unadjusted Inverse Hazard Ratio (95% CI)	0.57 (0.33, 1.00)		0.37 (0.20, 0.69)		
P-value for interaction test					0.34

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusions of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-any-tfr-sub.sas V.03.05 Output file: t-tte-any-tfr-sex.pdf 24AUG2023:12:44

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Table 2.4310: Analysis of Time to Any Type Transfusion Free Response by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Subjects with Event					
Any Type Transfusion Free Response, n(%)	31 (66.0%)	12 (27.9%)	21 (53.8%)	27 (52.9%)	
Censor					
Subjects Censored, n(%)	16 (34.0%)	31 (72.1%)	18 (46.2%)	24 (47.1%)	
Kaplan-Meier Estimate of Time to Any Type Transfusion Free Response (Weeks)					
25-percentile (95% CI)	12.14 (NE, NE)	20.14 (12.14, NE)	12.14 (12.14, 12.43)	12.14 (12.14, 17.29)	
Median (95% CI)	12.14 (12.14, 14.00)	NE (NE, NE)	22.86 (12.14, NE)	22.29 (17.29, NE)	
75-percentile (95% CI)	24.14 (12.14, NE)	NE (NE, NE)	NE (23.43, NE)	NE (NE, NE)	
Min, Max	1.29, 24.57	12.14, 27.00	1.29, 24.57	11.14, 24.57	
Stratified Log-Rank Test p-value	< 0.001		0.33		
Adjusted Inverse Hazard Ratio (95% CI)	0.18 (0.09, 0.36)		0.70 (0.38, 1.28)		
Unstratified Log-Rank Test p-value	< 0.001		0.61		
Unadjusted Inverse Hazard Ratio (95% CI)	0.25 (0.13, 0.49)		0.86 (0.49, 1.52)		
P-value for interaction test					0.004

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusions of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-any-tfr-sub.sas V.03.05 Output file: t-tte-any-tfr-svb.pdf 24AUG2023:12:44

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Table 2.4309: Analysis of Time to Any Type Transfusion Free Response by Baseline TSS

Double-blind Phase

ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Subjects with Event					
Any Type Transfusion Free Response, n(%)	29 (65.9%)	24 (43.6%)	22 (53.7%)	15 (39.5%)	
Censor					
Subjects Censored, n(%)	15 (34.1%)	31 (56.4%)	19 (46.3%)	23 (60.5%)	
Kaplan-Meier Estimate of Time to Any Type Transfusion Free Response (Weeks)					
25-percentile (95% CI)	12.14 (NE, NE)	12.14 (12.14, 20.29)	12.14 (NE, NE)	12.14 (12.14, 22.71)	
Median (95% CI)	12.29 (12.14, 22.14)	NE (20.29, NE)	12.14 (12.14, 24.14)	NE (17.29, NE)	
75-percentile (95% CI)	NE (21.86, NE)	NE (NE, NE)	NE (12.71, NE)	NE (NE, NE)	
Min, Max	1.29, 24.57	11.14, 26.71	1.29, 24.57	12.00, 27.00	
Stratified Log-Rank Test p-value	0.005		0.008		
Adjusted Inverse Hazard Ratio (95% CI)	0.42 (0.24, 0.73)		0.35 (0.17, 0.69)		
Unstratified Log-Rank Test p-value	0.011		0.034		
Unadjusted Inverse Hazard Ratio (95% CI)	0.50 (0.29, 0.86)		0.49 (0.25, 0.94)		
P-value for interaction test					0.98

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusions of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019

Table 2.4301: Analysis of Time to Any Type Transfusion Free Response
Double-blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Subjects with Event		
Any Type Transfusion Free Response, n(%)	52 (60.5%)	39 (41.5%)
Censor		
Subjects Censored, n(%)	34 (39.5%)	55 (58.5%)
Kaplan-Meier Estimate of Time to Any Type Transfusion Free Response (Weeks)		
25-percentile (95% CI)	12.14 (NE, NE)	12.14 (12.14, 20.14)
Median (95% CI)	12.21 (12.14, 22.00)	NE (22.00, NE)
75-percentile (95% CI)	NE (23.14, NE)	NE (NE, NE)
Min, Max	1.29, 24.57	11.14, 27.00
Stratified Log-Rank Test p-value	< 0.001	
Adjusted Inverse Hazard Ratio (95% CI)	0.38 (0.25, 0.59)	
Unstratified Log-Rank Test p-value	< 0.001	
Unadjusted Inverse Hazard Ratio (95% CI)	0.48 (0.32, 0.73)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusions of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
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Table 2.2502: Analysis of Time to RBC Transfusion Free Response by Age
Double-blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Subjects with Event					
RBC Transfusion Free Response, n(%)	18 (75.0%)	19 (52.8%)	34 (54.8%)	20 (34.5%)	
Censor					
Subjects Censored, n(%)	6 (25.0%)	17 (47.2%)	28 (45.2%)	38 (65.5%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Free Response (Weeks)					
25-percentile (95% CI)	12.14 (NE, NE)	12.14 (12.14, 18.00)	12.14 (NE, NE)	19.43 (12.14, NE)	
Median (95% CI)	12.14 (12.14, 14.14)	22.29 (12.14, NE)	14.00 (12.14, 23.14)	NE (NE, NE)	
75-percentile (95% CI)	24.14 (12.14, NE)	NE (NE, NE)	NE (23.14, NE)	NE (NE, NE)	
Min, Max	5.29, 24.57	11.14, 24.57	1.29, 24.57	12.00, 27.00	
Stratified Log-Rank Test p-value	0.10		< 0.001		
Adjusted Inverse Hazard Ratio (95% CI)	0.48 (0.24, 0.96)		0.30 (0.17, 0.55)		
Unstratified Log-Rank Test p-value	0.069		0.002		
Unadjusted Inverse Hazard Ratio (95% CI)	0.55 (0.29, 1.06)		0.42 (0.24, 0.73)		
P-value for interaction test					0.34

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-tfr-sub.sas V.03.05 Output file: t-tte-tfr-age.pdf 24AUG2023:11:02

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Table 2.2504: Analysis of Time to RBC Transfusion Free Response by Region
Double-blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Subjects with Event					
RBC Transfusion Free Response, n(%)	28 (52.8%)	18 (35.3%)	24 (72.7%)	21 (48.8%)	
Censor					
Subjects Censored, n(%)	25 (47.2%)	33 (64.7%)	9 (27.3%)	22 (51.2%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Free Response (Weeks)					
25-percentile (95% CI)	12.14 (NE, NE)	17.00 (12.14, 22.29)	12.14 (NE, NE)	12.14 (12.14, 20.43)	
Median (95% CI)	14.00 (12.14, NE)	NE (20.71, NE)	12.14 (12.14, 21.86)	NE (20.00, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	23.43 (12.14, NE)	NE (NE, NE)	
Min, Max	1.29, 24.57	11.14, 27.00	2.71, 24.57	12.14, 25.14	
Stratified Log-Rank Test p-value	0.003		0.002		
Adjusted Inverse Hazard Ratio (95% CI)	0.36 (0.20, 0.68)		0.34 (0.18, 0.62)		
Unstratified Log-Rank Test p-value	0.021		0.004		
Unadjusted Inverse Hazard Ratio (95% CI)	0.50 (0.28, 0.91)		0.42 (0.23, 0.76)		
P-value for interaction test					0.88

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-tfr-sub.sas V.03.05 Output file: t-tte-tfr-geo.pdf 24AUG2023:11:02

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Table 2.2507: Analysis of Time to RBC Transfusion Free Response by Baseline Hemoglobin Level
Double-blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Subjects with Event					
RBC Transfusion Free Response, n(%)	12 (42.9%)	5 (23.8%)	40 (69.0%)	34 (46.6%)	
Censor					
Subjects Censored, n(%)	16 (57.1%)	16 (76.2%)	18 (31.0%)	39 (53.4%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Free Response (Weeks)					
25-percentile (95% CI)	12.14 (12.14, 23.14)	20.71 (12.14, NE)	12.14 (NE, NE)	12.14 (12.14, 20.00)	
Median (95% CI)	24.14 (12.71, NE)	NE (20.71, NE)	12.14 (12.14, 12.43)	NE (20.29, NE)	
75-percentile (95% CI)	NE (24.14, NE)	NE (NE, NE)	22.86 (12.29, NE)	NE (NE, NE)	
Min, Max	1.29, 24.43	11.14, 24.57	1.29, 24.57	12.14, 27.00	
Stratified Log-Rank Test p-value	0.13		< 0.001		
Adjusted Inverse Hazard Ratio (95% CI)	0.46 (0.16, 1.32)		0.37 (0.23, 0.59)		
Unstratified Log-Rank Test p-value	0.13		< 0.001		
Unadjusted Inverse Hazard Ratio (95% CI)	0.46 (0.16, 1.32)		0.43 (0.27, 0.69)		
P-value for interaction test					0.69

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-tfr-sub.sas V.03.05 Output file: t-tte-tfr-hgb.pdf 24AUG2023:11:02

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Table 2.2506: Analysis of Time to RBC Transfusion Free Response by Baseline IPSS Two-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Subjects with Event					
RBC Transfusion Free Response, n(%)	19 (67.9%)	10 (41.7%)	33 (56.9%)	29 (41.4%)	
Censor					
Subjects Censored, n(%)	9 (32.1%)	14 (58.3%)	25 (43.1%)	41 (58.6%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Free Response (Weeks)					
25-percentile (95% CI)	12.14 (NE, NE)	12.14 (12.14, 22.29)	12.14 (NE, NE)	12.14 (12.14, 20.29)	
Median (95% CI)	12.14 (12.14, 16.29)	NE (12.14, NE)	14.00 (12.14, 23.57)	NE (20.71, NE)	
75-percentile (95% CI)	22.14 (12.14, NE)	NE (NE, NE)	NE (23.43, NE)	NE (NE, NE)	
Min, Max	2.71, 24.57	11.14, 25.14	1.29, 24.57	12.00, 27.00	
Stratified Log-Rank Test p-value	0.004		0.005		
Adjusted Inverse Hazard Ratio (95% CI)	0.28 (0.13, 0.65)		0.42 (0.25, 0.71)		
Unstratified Log-Rank Test p-value	0.017		0.013		
Unadjusted Inverse Hazard Ratio (95% CI)	0.41 (0.19, 0.89)		0.53 (0.32, 0.87)		
P-value for interaction test					0.52

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-tfr-sub.sas V.03.05 Output file: t-tte-tfr-ipss2.pdf 24AUG2023:11:02

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Table 2.2505: Analysis of Time to RBC Transfusion Free Response by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Subjects with Event				
RBC Transfusion Free Response, n(%)	2 (100.0%)	2 (50.0%)	17 (65.4%)	8 (40.0%)
Censor				
Subjects Censored, n(%)	0	2 (50.0%)	9 (34.6%)	12 (60.0%)
Kaplan-Meier Estimate of Time to RBC Transfusion Free Response (Weeks)				
25-percentile (95% CI)	12.14 (NE, NE)	17.07 (12.14, NE)	12.14 (NE, NE)	12.14 (12.14, NE)
Median (95% CI)	12.14 (NE, NE)	NE (12.14, NE)	12.14 (12.14, 16.29)	NE (12.14, NE)
75-percentile (95% CI)	12.14 (NE, NE)	NE (12.14, NE)	NE (12.29, NE)	NE (NE, NE)
Min, Max	12.14, 12.14	12.14, 24.14	2.71, 24.57	11.14, 25.14
Stratified Log-Rank Test p-value	NA		NA	
Adjusted Inverse Hazard Ratio (95% CI)	NA		NA	
Unstratified Log-Rank Test p-value	NA		NA	
Unadjusted Inverse Hazard Ratio (95% CI)	NA		NA	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment. P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-tfr-sub.sas V.03.05 Output file: t-tte-tfr-ipss3.pdf 24AUG2023:11:02

Table 2.2505: Analysis of Time to RBC Transfusion Free Response by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=58)	High Risk RUX (N=70)	p-value
Subjects with Event			
RBC Transfusion Free Response, n(%)	33 (56.9%)	29 (41.4%)	
Censor			
Subjects Censored, n(%)	25 (43.1%)	41 (58.6%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Free Response (Weeks)			
25-percentile (95% CI)	12.14 (NE, NE)	12.14 (12.14, 20.29)	
Median (95% CI)	14.00 (12.14, 23.57)	NE (20.71, NE)	
75-percentile (95% CI)	NE (23.43, NE)	NE (NE, NE)	
Min, Max	1.29, 24.57	12.00, 27.00	
Stratified Log-Rank Test p-value	NA		
Adjusted Inverse Hazard Ratio (95% CI)	NA		
Unstratified Log-Rank Test p-value	NA		
Unadjusted Inverse Hazard Ratio (95% CI)	NA		
P-value for interaction test			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-tfr-sub.sas V.03.05 Output file: t-tte-tfr-ipss3.pdf 24AUG2023:11:02

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Table 2.2508: Analysis of Time to RBC Transfusion Free Response by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=16)	RUX (N=28)	MMB (N=11)	RUX (N=12)
Subjects with Event				
RBC Transfusion Free Response, n(%)	8 (50.0%)	10 (35.7%)	6 (54.5%)	2 (16.7%)
Censor				
Subjects Censored, n(%)	8 (50.0%)	18 (64.3%)	5 (45.5%)	10 (83.3%)
Kaplan-Meier Estimate of Time to RBC Transfusion Free Response (Weeks)				
25-percentile (95% CI)	12.14 (12.14, 12.29)	12.14 (12.14, NE)	12.14 (NE, NE)	NE (12.14, NE)
Median (95% CI)	12.36 (12.14, NE)	NE (12.14, NE)	12.14 (12.14, NE)	NE (12.14, NE)
75-percentile (95% CI)	NE (12.29, NE)	NE (NE, NE)	NE (12.14, NE)	NE (NE, NE)
Min, Max	1.29, 24.57	11.14, 27.00	1.29, 24.29	12.14, 24.29
Stratified Log-Rank Test p-value	0.077		0.024	
Adjusted Inverse Hazard Ratio (95% CI)	0.37 (0.13, 1.02)		0.12 (0.02, 0.70)	
Unstratified Log-Rank Test p-value	0.26		0.010	
Unadjusted Inverse Hazard Ratio (95% CI)	0.62 (0.24, 1.56)		0.16 (0.03, 0.78)	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment. P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-tfr-sub.sas V.03.05 Output file: t-tte-tfr-mf.pdf 24AUG2023:11:02

Table 2.2508: Analysis of Time to RBC Transfusion Free Response by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	Primary Myelofibrosis MMB (N=59)	Primary Myelofibrosis RUX (N=54)	p-value
Subjects with Event			
RBC Transfusion Free Response, n(%)	38 (64.4%)	27 (50.0%)	
Censor			
Subjects Censored, n(%)	21 (35.6%)	27 (50.0%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Free Response (Weeks)			
25-percentile (95% CI)	12.14 (NE, NE)	12.14 (12.14, 20.14)	
Median (95% CI)	12.43 (12.14, 22.86)	22.71 (20.00, NE)	
75-percentile (95% CI)	NE (22.86, NE)	NE (NE, NE)	
Min, Max	2.29, 24.57	12.14, 25.14	
Stratified Log-Rank Test p-value	0.028		
Adjusted Inverse Hazard Ratio (95% CI)	0.47 (0.28, 0.78)		
Unstratified Log-Rank Test p-value	0.029		
Unadjusted Inverse Hazard Ratio (95% CI)	0.56 (0.34, 0.92)		
P-value for interaction test			0.14

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-tfr-sub.sas V.03.05 Output file: t-tte-tfr-mf.pdf 24AUG2023:11:02

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Table 2.2503: Analysis of Time to RBC Transfusion Free Response by Gender
Double-blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Subjects with Event					
RBC Transfusion Free Response, n(%)	28 (56.0%)	22 (39.3%)	24 (66.7%)	17 (44.7%)	
Censor					
Subjects Censored, n(%)	22 (44.0%)	34 (60.7%)	12 (33.3%)	21 (55.3%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Free Response (Weeks)					
25-percentile (95% CI)	12.14 (NE, NE)	18.00 (12.14, 22.29)	12.14 (NE, NE)	12.14 (12.14, 20.43)	
Median (95% CI)	21.86 (12.14, NE)	NE (20.71, NE)	12.14 (NE, NE)	NE (12.14, NE)	
75-percentile (95% CI)	NE (23.57, NE)	NE (NE, NE)	22.14 (12.14, NE)	NE (NE, NE)	
Min, Max	2.29, 24.57	11.14, 26.71	1.29, 24.57	12.14, 27.00	
Stratified Log-Rank Test p-value	0.015		0.004		
Adjusted Inverse Hazard Ratio (95% CI)	0.45 (0.25, 0.80)		0.32 (0.17, 0.62)		
Unstratified Log-Rank Test p-value	0.049		0.001		
Unadjusted Inverse Hazard Ratio (95% CI)	0.57 (0.33, 1.00)		0.37 (0.20, 0.69)		
P-value for interaction test					0.34

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-tfr-sub.sas V.03.05 Output file: t-tte-tfr-sex.pdf 24AUG2023:11:02

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Table 2.2510: Analysis of Time to RBC Transfusion Free Response by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Subjects with Event					
RBC Transfusion Free Response, n(%)	31 (66.0%)	12 (27.9%)	21 (53.8%)	27 (52.9%)	
Censor					
Subjects Censored, n(%)	16 (34.0%)	31 (72.1%)	18 (46.2%)	24 (47.1%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Free Response (Weeks)					
25-percentile (95% CI)	12.14 (NE, NE)	20.14 (12.14, NE)	12.14 (12.14, 12.43)	12.14 (12.14, 17.29)	
Median (95% CI)	12.14 (12.14, 14.00)	NE (NE, NE)	22.86 (12.14, NE)	22.29 (17.29, NE)	
75-percentile (95% CI)	24.14 (12.14, NE)	NE (NE, NE)	NE (23.43, NE)	NE (NE, NE)	
Min, Max	1.29, 24.57	12.14, 27.00	1.29, 24.57	11.14, 24.57	
Stratified Log-Rank Test p-value	< 0.001		0.33		
Adjusted Inverse Hazard Ratio (95% CI)	0.18 (0.09, 0.36)		0.70 (0.38, 1.28)		
Unstratified Log-Rank Test p-value	< 0.001		0.61		
Unadjusted Inverse Hazard Ratio (95% CI)	0.25 (0.13, 0.49)		0.86 (0.49, 1.52)		
P-value for interaction test					0.004

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-tfr-sub.sas V.03.05 Output file: t-tte-tfr-svb.pdf 24AUG2023:11:02

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Table 2.2509: Analysis of Time to RBC Transfusion Free Response by Baseline TSS
Double-blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Subjects with Event					
RBC Transfusion Free Response, n(%)	29 (65.9%)	24 (43.6%)	22 (53.7%)	15 (39.5%)	
Censor					
Subjects Censored, n(%)	15 (34.1%)	31 (56.4%)	19 (46.3%)	23 (60.5%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Free Response (Weeks)					
25-percentile (95% CI)	12.14 (NE, NE)	12.14 (12.14, 20.29)	12.14 (NE, NE)	12.14 (12.14, 22.71)	
Median (95% CI)	12.29 (12.14, 22.14)	NE (20.29, NE)	12.14 (12.14, 24.14)	NE (17.29, NE)	
75-percentile (95% CI)	NE (21.86, NE)	NE (NE, NE)	NE (12.71, NE)	NE (NE, NE)	
Min, Max	1.29, 24.57	11.14, 26.71	1.29, 24.57	12.00, 27.00	
Stratified Log-Rank Test p-value	0.005		0.008		
Adjusted Inverse Hazard Ratio (95% CI)	0.42 (0.24, 0.73)		0.35 (0.17, 0.69)		
Unstratified Log-Rank Test p-value	0.011		0.034		
Unadjusted Inverse Hazard Ratio (95% CI)	0.50 (0.29, 0.86)		0.49 (0.25, 0.94)		
P-value for interaction test					0.98

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-tfr-sub.sas V.03.05 Output file: t-tte-tfr-tss.pdf 24AUG2023:11:02

Table 2.2501: Analysis of Time to RBC Transfusion Free Response
Double-blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Subjects with Event		
RBC Transfusion Free Response, n(%)	52 (60.5%)	39 (41.5%)
Censor		
Subjects Censored, n(%)	34 (39.5%)	55 (58.5%)
Kaplan-Meier Estimate of Time to RBC Transfusion Free Response (Weeks)		
25-percentile (95% CI)	12.14 (NE, NE)	12.14 (12.14, 20.14)
Median (95% CI)	12.21 (12.14, 22.00)	NE (22.00, NE)
75-percentile (95% CI)	NE (23.14, NE)	NE (NE, NE)
Min, Max	1.29, 24.57	11.14, 27.00
Stratified Log-Rank Test p-value	< 0.001	
Adjusted Inverse Hazard Ratio (95% CI)	0.38 (0.25, 0.59)	
Unstratified Log-Rank Test p-value	< 0.001	
Unadjusted Inverse Hazard Ratio (95% CI)	0.48 (0.32, 0.73)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-tte-tfr.sas V.03.05 Output file: t-tte-tfr.pdf 24AUG2023:11:02

1.6.3 TD

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Table 2.3911: Analysis of Rate of New RBC Transfusion Dependent by Week 24
Double-Blind Phase
ITT-Anemic Analysis Set Who are not Transfusion Dependent at Baseline

	MMB (N=37)	RUX (N=51)	Total (N=88)
RBC Transfusion Dependent Rate by Week 24			
Not-Dependent, n(%)	24 (64.9%)	14 (27.5%)	38 (43.2%)
Dependent, n(%)	13 (35.1%)	37 (72.5%)	50 (56.8%)
95% Exact CI	0.2021, 0.5254	0.5826, 0.8411	0.4582, 0.6734
Proportion Difference - Stratified CMH Method (95% CI)	-0.38 (-0.59, -0.18)		
p-value	<0.001		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.37 (-0.57, -0.17)		
p-value	<0.001		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.37 (-0.56, -0.17)		
p-value	<0.001		
Unadjusted Relative Risk (95% CI)	0.48 (0.30, 0.77)		
p-value [1]	0.002		
Unadjusted Odds Ratio (95% CI)	0.20 (0.08, 0.51)		
p-value [1]	<0.001		
Unadjusted Absolute Risk Difference (95% CI)	-0.37 (-0.57, -0.18)		
Adjusted Relative Risk (95% CI) [2]	0.48 (0.30, 0.77)		
p-value [2]	0.002		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-new-rbctd-by24-gba.sas V.03.05 Output file: t-new-rbctd-by24-gba.pdf 29AUG2023: 8:59

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Table 2.3812: Analysis of RBC Transfusion Dependence Rate at Week 24 and Week 12

Double-Blind Phase

ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
All Strata Combined			
RBC Transfusion Dependent Rate at Week 24			
Not-Dependent, n(%)	26 (42.6%)	17 (32.1%)	43 (37.7%)
Transfusion Requiring, n(%)	4 (6.6%)	6 (11.3%)	10 (8.8%)
Transfusion Independent, n(%)	22 (36.1%)	11 (20.8%)	33 (28.9%)
Dependent, n(%)	35 (57.4%)	36 (67.9%)	71 (62.3%)
95% Exact CI	0.4406, 0.6996	0.5368, 0.8008	0.5272, 0.7119
Proportion Difference - Stratified CMH Method (95% CI)	-0.11 (-0.29, 0.07)		
p-value	0.23		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.11 (-0.28, 0.07)		
p-value	0.25		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.11 (-0.28, 0.08)		
p-value	0.33		
Unadjusted Relative Risk (95% CI)	0.84 (0.64, 1.12)		
p-value [1]	0.25		
Unadjusted Odds Ratio (95% CI)	0.64 (0.29, 1.37)		
p-value [1]	0.25		
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.28, 0.07)		
Adjusted Relative Risk (95% CI) [2]	0.84 (0.64, 1.11)		
p-value [2]	0.21		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.

CMH = Cochran-Mantel-Haenszel.

RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

Table 2.3812: Analysis of RBC Transfusion Dependence Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
>=4 units transfused in the last 8 weeks	14 (23.0%)	19 (35.8%)	33 (28.9%)
Any Hgb assessment < 8g/dL in the last 8 weeks	18 (29.5%)	25 (47.2%)	43 (37.7%)
Last Participation date < Day 162 in DB phase	12 (19.7%)	7 (13.2%)	19 (16.7%)
Other	11 (18.0%)	16 (30.2%)	27 (23.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
Data Extracted: CRF data: 01JUL2019
Source: t-rbctd24-gba.sas V.03.05 Output file: t-rbctd24-nti-gba.pdf 29AUG2023: 9:36

Table 2.3812: Analysis of RBC Transfusion Dependence Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
RBC Transfusion Dependent Rate at Week 12			
Not-Dependent, n(%)	29 (47.5%)	10 (18.9%)	39 (34.2%)
Transfusion Requiring, n(%)	15 (24.6%)	4 (7.5%)	19 (16.7%)
Transfusion Independent, n(%)	14 (23.0%)	6 (11.3%)	20 (17.5%)
Dependent, n(%)	32 (52.5%)	43 (81.1%)	75 (65.8%)
95% Exact CI	0.3927, 0.6540	0.6803, 0.9056	0.5632, 0.7442
Proportion Difference - Stratified CMH Method (95% CI)	-0.28 (-0.45, -0.12)		
p-value	<0.001		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.29 (-0.45, -0.12)		
p-value	<0.001		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.29 (-0.45, -0.10)		
p-value	0.002		
Unadjusted Relative Risk (95% CI)	0.65 (0.49, 0.85)		
p-value [1]	0.002		
Unadjusted Odds Ratio (95% CI)	0.26 (0.11, 0.60)		
p-value [1]	0.002		
Unadjusted Absolute Risk Difference (95% CI)	-0.29 (-0.45, -0.12)		
Adjusted Relative Risk (95% CI) [2]	0.65 (0.50, 0.85)		
p-value [2]	0.001		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
Data Extracted: CRF data: 01JUL2019
Source: t-rbctd24-gba.sas V.03.05 Output file: t-rbctd24-nti-gba.pdf 29AUG2023: 9:36

Table 2.3812: Analysis of RBC Transfusion Dependence Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
>=4 units transfused in the last 8 weeks	21 (34.4%)	29 (54.7%)	50 (43.9%)
Any Hgb assessment < 8g/dL in the last 8 weeks	21 (34.4%)	41 (77.4%)	62 (54.4%)
Last Participation date < Day 78 in DB phase	7 (11.5%)	0	7 (6.1%)
Other	10 (16.4%)	26 (49.1%)	36 (31.6%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
Data Extracted: CRF data: 01JUL2019
Source: t-rbctd24-gba.sas V.03.05 Output file: t-rbctd24-nti-gba.pdf 29AUG2023: 9:36

Table 1.02: Analysis of RBC Transfusion Dependence Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	MMB (N=49)	RUX (N=43)	Total (N=92)
All Strata Combined			
RBC Transfusion Dependent Rate at Week 24			
Not-Dependent, n(%)	20 (40.8%)	12 (27.9%)	32 (34.8%)
Transfusion Requiring, n(%)	4 (8.2%)	4 (9.3%)	8 (8.7%)
Transfusion Independent, n(%)	16 (32.7%)	8 (18.6%)	24 (26.1%)
Dependent, n(%)	29 (59.2%)	31 (72.1%)	60 (65.2%)
95% Exact CI	0.4421, 0.7300	0.5633, 0.8467	0.5457, 0.7485
Proportion Difference - Stratified CMH Method (95% CI)	-0.13 (-0.33, 0.06)		
p-value	0.18		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.13 (-0.32, 0.07)		
p-value	0.19		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.13 (-0.33, 0.08)		
p-value	0.27		
Unadjusted Relative Risk (95% CI)	0.82 (0.61, 1.11)		
p-value [1]	0.19		
Unadjusted Odds Ratio (95% CI)	0.56 (0.23, 1.35)		
p-value [1]	0.20		
Unadjusted Absolute Risk Difference (95% CI)	-0.13 (-0.32, 0.06)		
Adjusted Relative Risk (95% CI) [2]	0.82 (0.61, 1.09)		
p-value [2]	0.17		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
Data Extracted: CRF data: 01JUL2019
Source: t-rbctd24-nti-gba.sas vV.03.05 Output file: t-rbctd24-nti-gba.pdf 25OCT2023:12:30

Table 1.02: Analysis of RBC Transfusion Dependence Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	MMB (N=49)	RUX (N=43)	Total (N=92)
>=4 units transfused in the last 8 weeks	12 (24.5%)	16 (37.2%)	28 (30.4%)
Any Hgb assessment < 8g/dL in the last 8 weeks	17 (34.7%)	21 (48.8%)	38 (41.3%)
Last Participation date < Day 162 in DB phase	9 (18.4%)	7 (16.3%)	16 (17.4%)
Other	11 (22.4%)	15 (34.9%)	26 (28.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
Data Extracted: CRF data: 01JUL2019

Table 1.02: Analysis of RBC Transfusion Dependence Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	MMB (N=49)	RUX (N=43)	Total (N=92)
RBC Transfusion Dependent Rate at Week 12			
Not-Dependent, n(%)	20 (40.8%)	7 (16.3%)	27 (29.3%)
Transfusion Requiring, n(%)	11 (22.4%)	3 (7.0%)	14 (15.2%)
Transfusion Independent, n(%)	9 (18.4%)	4 (9.3%)	13 (14.1%)
Dependent, n(%)	29 (59.2%)	36 (83.7%)	65 (70.7%)
95% Exact CI	0.4421, 0.7300	0.6930, 0.9319	0.6024, 0.7969
Proportion Difference - Stratified CMH Method (95% CI)	-0.24 (-0.43, -0.06)		
p-value	0.010		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.25 (-0.43, -0.07)		
p-value	0.007		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.25 (-0.43, -0.04)		
p-value	0.012		
Unadjusted Relative Risk (95% CI)	0.71 (0.54, 0.92)		
p-value [1]	0.011		
Unadjusted Odds Ratio (95% CI)	0.28 (0.10, 0.76)		
p-value [1]	0.012		
Unadjusted Absolute Risk Difference (95% CI)	-0.25 (-0.42, -0.07)		
Adjusted Relative Risk (95% CI) [2]	0.71 (0.54, 0.92)		
p-value [2]	0.011		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
Data Extracted: CRF data: 01JUL2019
Source: t-rbctd24-nti-gba.sas vV.03.05 Output file: t-rbctd24-nti-gba.pdf 25OCT2023:12:30

Table 1.02: Analysis of RBC Transfusion Dependence Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	MMB (N=49)	RUX (N=43)	Total (N=92)
>=4 units transfused in the last 8 weeks	18 (36.7%)	25 (58.1%)	43 (46.7%)
Any Hgb assessment < 8g/dL in the last 8 weeks	19 (38.8%)	35 (81.4%)	54 (58.7%)
Last Participation date < Day 78 in DB phase	7 (14.3%)	0	7 (7.6%)
Other	9 (18.4%)	25 (58.1%)	34 (37.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
Data Extracted: CRF data: 01JUL2019
Source: t-rbctd24-nti-gba.sas vV.03.05 Output file: t-rbctd24-nti-gba.pdf 25OCT2023:12:30

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Table 2.3811: Analysis of RBC Transfusion Dependence Rate at Week 24 and Week 12

Double-Blind Phase

ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=25)	RUX (N=41)	Total (N=66)
All Strata Combined			
RBC Transfusion Dependent Rate at Week 24			
Not-Dependent, n(%)	19 (76.0%)	19 (46.3%)	38 (57.6%)
Transfusion Requiring, n(%)	1 (4.0%)	5 (12.2%)	6 (9.1%)
Transfusion Independent, n(%)	18 (72.0%)	14 (34.1%)	32 (48.5%)
Dependent, n(%)	6 (24.0%)	22 (53.7%)	28 (42.4%)
95% Exact CI	0.0936, 0.4513	0.3742, 0.6934	0.3034, 0.5521
Proportion Difference - Stratified CMH Method (95% CI)	-0.28 (-0.52, -0.04)		
p-value	0.023		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.30 (-0.53, -0.06)		
p-value	0.012		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.30 (-0.52, -0.05)		
p-value	0.022		
Unadjusted Relative Risk (95% CI)	0.45 (0.21, 0.95)		
p-value [1]	0.036		
Unadjusted Odds Ratio (95% CI)	0.27 (0.09, 0.82)		
p-value [1]	0.021		
Unadjusted Absolute Risk Difference (95% CI)	-0.30 (-0.52, -0.07)		
Adjusted Relative Risk (95% CI) [2]	0.46 (0.21, 1.01)		
p-value [2]	0.052		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.

CMH = Cochran-Mantel-Haenszel.

RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

Table 2.3811: Analysis of RBC Transfusion Dependence Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=25)	RUX (N=41)	Total (N=66)
>=4 units transfused in the last 8 weeks	0	10 (24.4%)	10 (15.2%)
Any Hgb assessment < 8g/dL in the last 8 weeks	2 (8.0%)	18 (43.9%)	20 (30.3%)
Last Participation date < Day 162 in DB phase	4 (16.0%)	1 (2.4%)	5 (7.6%)
Other	0	10 (24.4%)	10 (15.2%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
Data Extracted: CRF data: 01JUL2019

Table 2.3811: Analysis of RBC Transfusion Dependence Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=25)	RUX (N=41)	Total (N=66)
RBC Transfusion Dependent Rate at Week 12			
Not-Dependent, n(%)	**21 (84.0%)**	**17 (41.5%)**	**38 (57.6%)**
Transfusion Requiring, n(%)	**0**	**3 (7.3%)**	**3 (4.5%)**
Transfusion Independent, n(%)	**21 (84.0%)**	**14 (34.1%)**	**35 (53.0%)**
Dependent, n(%)	**4 (16.0%)**	**24 (58.5%)**	**28 (42.4%)**
95% Exact CI	**0.0454, 0.3608**	**0.4211, 0.7368**	**0.3034, 0.5521**
Proportion Difference - Stratified CMH Method (95% CI)	**-0.45 (-0.67, -0.23)**		
p-value	**<0.001**		
Proportion Difference - Unstratified CMH Method (95% CI)	**-0.43 (-0.64, -0.21)**		
p-value	**<0.001**		
Proportion Difference - Unstratified Exact Method (95% CI)	**-0.43 (-0.63, -0.18)**		
p-value	**<0.001**		
Unadjusted Relative Risk (95% CI)	**0.27 (0.11, 0.70)**		
p-value [1]	**0.007**		
Unadjusted Odds Ratio (95% CI)	**0.13 (0.04, 0.46)**		
p-value [1]	**0.002**		
Unadjusted Absolute Risk Difference (95% CI)	**-0.43 (-0.63, -0.22)**		
Adjusted Relative Risk (95% CI) [2]	**0.26 (0.10, 0.67)**		
p-value [2]	**0.005**		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
Data Extracted: CRF data: 01JUL2019

Table 2.3811: Analysis of RBC Transfusion Dependence Rate at Week 24 and Week 12
Double-Blind Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=25)	RUX (N=41)	Total (N=66)
>=4 units transfused in the last 8 weeks	0	9 (22.0%)	9 (13.6%)
Any Hgb assessment < 8g/dL in the last 8 weeks	0	22 (53.7%)	22 (33.3%)
Last Participation date < Day 78 in DB phase	3 (12.0%)	0	3 (4.5%)
Other	1 (4.0%)	9 (22.0%)	10 (15.2%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
Data Extracted: CRF data: 01JUL2019
Source: t-rbctd24-gba.sas V.03.05 Output file: t-rbctd24-ti-gba.pdf 29AUG2023: 9:36

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Table 2.3902: Analysis of Rate of RBC Transfusion Dependence by Week 24 by Age

Double-Blind Phase

ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
RBC Transfusion Dependent Rate by Week 24					
Not-Dependent, n(%)	8 (33.3%)	10 (27.8%)	26 (41.9%)	10 (17.2%)	
Dependent, n(%)	16 (66.7%)	26 (72.2%)	36 (58.1%)	48 (82.8%)	
95% Exact CI	0.4468, 0.8437	0.5481, 0.8580	0.4485, 0.7049	0.7057, 0.9141	
Proportion Difference - Stratified CMH Method (95% CI)	-0.01 (-0.27, 0.25)		-0.29 (-0.45, -0.12)		
p-value	0.93		<0.001		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.06 (-0.30, 0.19)		-0.25 (-0.41, -0.09)		
p-value	0.66		0.002		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.06 (-0.31, 0.21)		-0.25 (-0.41, -0.07)		
p-value	0.78		0.005		
Unadjusted Relative Risk (95% CI)	0.92 (0.65, 1.31)		0.70 (0.55, 0.89)		
p-value [1]	0.65		0.004		
Unadjusted interaction test for Treatment*Age Group [3]					0.22
Unadjusted Odds Ratio (95% CI)	0.77 (0.25, 2.36)		0.29 (0.12, 0.67)		
p-value [1]	0.65		0.004		
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.29, 0.18)		-0.25 (-0.40, -0.09)		
Adjusted Relative Risk (95% CI) [2]	0.98 (0.73, 1.34)		0.66 (0.52, 0.83)		
p-value [2]	0.92		<0.001		
Adjusted interaction test for Treatment*Age Group [3]					0.13

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel; RBC = Red Blood Cell

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

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Table 2.3908: Analysis of Rate of RBC Transfusion Dependence by Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
RBC Transfusion Dependent Rate by Week 24				
Not-Dependent, n(%)	24 (40.7%)	10 (18.5%)	5 (31.3%)	7 (25.0%)
Dependent, n(%)	35 (59.3%)	44 (81.5%)	11 (68.8%)	21 (75.0%)
95% Exact CI	0.4575, 0.7193	0.6857, 0.9075	0.4134, 0.8898	0.5513, 0.8931
Proportion Difference - Stratified CMH Method (95% CI)	-0.23 (-0.40, -0.07)		-0.08 (-0.37, 0.21)	
p-value	0.005		0.58	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.22 (-0.39, -0.06)		-0.06 (-0.35, 0.23)	
p-value	0.008		0.67	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.22 (-0.40, -0.04)		-0.06 (-0.36, 0.25)	
p-value	0.014		0.73	
Unadjusted Relative Risk (95% CI)	0.73 (0.57, 0.93)		0.92 (0.62, 1.36)	
p-value [1]	0.012		0.66	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	0.33 (0.14, 0.78)		0.73 (0.19, 2.86)	
p-value [1]	0.012		0.65	
Unadjusted Absolute Risk Difference (95% CI)	-0.22 (-0.38, -0.06)		-0.06 (-0.34, 0.22)	
Adjusted Relative Risk (95% CI) [2]	0.72 (0.56, 0.91)		0.90 (0.64, 1.26)	
p-value [2]	0.007		0.52	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel; RBC = Red Blood Cell
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbctd-by24-gba.sas V.03.05 Output file: t-rbctd-by24-gba-dstat.pdf 29AUG2023: 9:01

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Table 2.3908: Analysis of Rate of RBC Transfusion Dependence by Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	RUX (N=12)	p-value
RBC Transfusion Dependent Rate by Week 24			
Not-Dependent, n(%)	5 (45.5%)	3 (25.0%)	
Dependent, n(%)	6 (54.5%)	9 (75.0%)	
95% Exact CI	0.2338, 0.8325	0.4281, 0.9451	
Proportion Difference - Stratified CMH Method (95% CI)	-0.27 (-0.73, 0.20)		
p-value	0.26		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.20 (-0.61, 0.20)		
p-value	0.32		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.20 (-0.57, 0.23)		
p-value	0.40		
Unadjusted Relative Risk (95% CI)	0.73 (0.39, 1.37)		
p-value [1]	0.32		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.63
Unadjusted Odds Ratio (95% CI)	0.40 (0.07, 2.34)		
p-value [1]	0.31		
Unadjusted Absolute Risk Difference (95% CI)	-0.20 (-0.59, 0.18)		
Adjusted Relative Risk (95% CI) [2]	0.66 (0.35, 1.25)		
p-value [2]	0.20		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.57

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel; RBC = Red Blood Cell
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbctd-by24-gba.sas V.03.05 Output file: t-rbctd-by24-gba-dstat.pdf 29AUG2023: 9:01

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Table 2.3907: Analysis of Rate of RBC Transfusion Dependence by Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
RBC Transfusion Dependent Rate by Week 24					
Not-Dependent, n(%)	4 (14.3%)	2 (9.5%)	30 (51.7%)	18 (24.7%)	
Dependent, n(%)	24 (85.7%)	19 (90.5%)	28 (48.3%)	55 (75.3%)	
95% Exact CI	0.6733, 0.9597	0.6962, 0.9883	0.3495, 0.6178	0.6386, 0.8468	
Proportion Difference - Stratified CMH Method (95% CI)	-0.05 (-0.27, 0.17)		-0.29 (-0.46, -0.12)		
p-value	0.68		<0.001		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.05 (-0.24, 0.15)		-0.27 (-0.43, -0.11)		
p-value	0.63		0.001		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.05 (-0.33, 0.24)		-0.27 (-0.43, -0.10)		
p-value	0.69		0.002		
Unadjusted Relative Risk (95% CI)	0.95 (0.77, 1.16)		0.64 (0.48, 0.86)		
p-value [1]	0.61		0.003		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.034
Unadjusted Odds Ratio (95% CI)	0.63 (0.10, 3.82)		0.31 (0.15, 0.64)		
p-value [1]	0.62		0.002		
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.23, 0.13)		-0.27 (-0.43, -0.11)		
Adjusted Relative Risk (95% CI) [2]	0.95 (0.78, 1.16)		0.62 (0.46, 0.83)		
p-value [2]	0.61		0.001		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.018

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel; RBC = Red Blood Cell
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbctd-by24-gba.sas V.03.05 Output file: t-rbctd-by24-gba-hgb.pdf 29AUG2023: 9:01

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Table 2.3906: Analysis of Rate of RBC Transfusion Dependence by Week 24 by Baseline IPSS Two-Level Risk

Double-Blind Phase

ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
RBC Transfusion Dependent Rate by Week 24					
Not-Dependent, n(%)	12 (42.9%)	6 (25.0%)	22 (37.9%)	14 (20.0%)	
Dependent, n(%)	16 (57.1%)	18 (75.0%)	36 (62.1%)	56 (80.0%)	
95% Exact CI	0.3718, 0.7554	0.5329, 0.9023	0.4837, 0.7449	0.6873, 0.8861	
Proportion Difference - Stratified CMH Method (95% CI)	-0.26 (-0.55, 0.02)		-0.19 (-0.35, -0.04)		
p-value	0.065		0.016		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.18 (-0.44, 0.08)		-0.18 (-0.34, -0.02)		
p-value	0.18		0.026		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.18 (-0.43, 0.10)		-0.18 (-0.34, -0.01)		
p-value	0.25		0.030		
Unadjusted Relative Risk (95% CI)	0.76 (0.51, 1.13)		0.78 (0.61, 0.98)		
p-value [1]	0.18		0.033		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.94
Unadjusted Odds Ratio (95% CI)	0.44 (0.14, 1.46)		0.41 (0.19, 0.90)		
p-value [1]	0.18		0.027		
Unadjusted Absolute Risk Difference (95% CI)	-0.18 (-0.43, 0.07)		-0.18 (-0.34, -0.02)		
Adjusted Relative Risk (95% CI) [2]	0.66 (0.47, 0.95)		0.76 (0.61, 0.95)		
p-value [2]	0.024		0.017		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.77

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel; RBC = Red Blood Cell

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

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Table 2.3905: Analysis of Rate of RBC Transfusion Dependence by Week 24 by Baseline IPSS Three-Level Risk

Double-Blind Phase

ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
RBC Transfusion Dependent Rate by Week 24				
Not-Dependent, n(%)	2 (100.0%)	1 (25.0%)	10 (38.5%)	5 (25.0%)
Dependent, n(%)	0	3 (75.0%)	16 (61.5%)	15 (75.0%)
95% Exact CI	0.0000, 0.8419	0.1941, 0.9937	0.4057, 0.7977	0.5090, 0.9134
Proportion Difference - Stratified CMH Method (95% CI)	-0.50 (-1.72, 0.72)		-0.21 (-0.48, 0.07)	
p-value	0.42		0.14	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.75 (-1.65, 0.15)		-0.13 (-0.41, 0.14)	
p-value	0.10		0.34	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.75 (-0.99, 0.23)		-0.13 (-0.41, 0.16)	
p-value	0.40		0.36	
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel; RBC = Red Blood Cell

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.3905: Analysis of Rate of RBC Transfusion Dependence by Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N=58)	RUX (N=70)	p-value
RBC Transfusion Dependent Rate by Week 24			
Not-Dependent, n(%)	22 (37.9%)	14 (20.0%)	
Dependent, n(%)	36 (62.1%)	56 (80.0%)	
95% Exact CI	0.4837, 0.7449	0.6873, 0.8861	
Proportion Difference - Stratified CMH Method (95% CI)	-0.19 (-0.35, -0.04)		
p-value	0.016		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.18 (-0.34, -0.02)		
p-value	0.026		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.18 (-0.34, -0.01)		
p-value	0.030		
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel; RBC = Red Blood Cell
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbctd-by24-gba.sas V.03.05 Output file: t-rbctd-by24-gba-ip3.pdf 29AUG2023: 9:01

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Table 2.3904: Analysis of Rate of RBC Transfusion Dependence by Week 24 by Region

Double-Blind Phase

ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
RBC Transfusion Dependent Rate by Week 24					
Not-Dependent, n(%)	18 (34.0%)	12 (23.5%)	16 (48.5%)	8 (18.6%)	
Dependent, n(%)	35 (66.0%)	39 (76.5%)	17 (51.5%)	35 (81.4%)	
95% Exact CI	0.5173, 0.7848	0.6251, 0.8721	0.3354, 0.6920	0.6660, 0.9161	
Proportion Difference - Stratified CMH Method (95% CI)	-0.17 (-0.35, 0.01)		-0.29 (-0.48, -0.10)		
p-value	0.066		0.003		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.10 (-0.28, 0.07)		-0.30 (-0.51, -0.09)		
p-value	0.24		0.005		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.10 (-0.29, 0.09)		-0.30 (-0.50, -0.07)		
p-value	0.28		0.007		
Unadjusted Relative Risk (95% CI)	0.86 (0.68, 1.10)		0.63 (0.44, 0.91)		
p-value [1]	0.24		0.013		
Unadjusted interaction test for Treatment*Region [3]					0.15
Unadjusted Odds Ratio (95% CI)	0.60 (0.25, 1.42)		0.24 (0.09, 0.68)		
p-value [1]	0.24		0.007		
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.28, 0.07)		-0.30 (-0.51, -0.09)		
Adjusted Relative Risk (95% CI) [2]	0.79 (0.63, 1.00)		0.64 (0.46, 0.88)		
p-value [2]	0.047		0.007		
Adjusted interaction test for Treatment*Region [3]					0.23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel; RBC = Red Blood Cell

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

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Table 2.3903: Analysis of Rate of RBC Transfusion Dependence by Week 24 by Gender

Double-Blind Phase

ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
RBC Transfusion Dependent Rate by Week 24					
Not-Dependent, n(%)	17 (34.0%)	10 (17.9%)	17 (47.2%)	10 (26.3%)	
Dependent, n(%)	33 (66.0%)	46 (82.1%)	19 (52.8%)	28 (73.7%)	
95% Exact CI	0.5123, 0.7879	0.6960, 0.9109	0.3549, 0.6959	0.5690, 0.8660	
Proportion Difference - Stratified CMH Method (95% CI)	-0.24 (-0.41, -0.08)		-0.18 (-0.42, 0.05)		
p-value	0.004		0.13		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.16 (-0.33, 0.01)		-0.21 (-0.43, 0.01)		
p-value	0.059		0.061		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.16 (-0.34, 0.03)		-0.21 (-0.42, 0.03)		
p-value	0.075		0.091		
Unadjusted Relative Risk (95% CI)	0.80 (0.64, 1.01)		0.72 (0.50, 1.03)		
p-value [1]	0.066		0.071		
Unadjusted interaction test for Treatment*Gender [3]					0.60
Unadjusted Odds Ratio (95% CI)	0.42 (0.17, 1.04)		0.40 (0.15, 1.06)		
p-value [1]	0.060		0.065		
Unadjusted Absolute Risk Difference (95% CI)	-0.16 (-0.33, 0.00)		-0.21 (-0.42, 0.01)		
Adjusted Relative Risk (95% CI) [2]	0.72 (0.58, 0.90)		0.74 (0.51, 1.08)		
p-value [2]	0.004		0.12		
Adjusted interaction test for Treatment*Gender [3]					1.00

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel; RBC = Red Blood Cell

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.3910: Analysis of Rate of RBC Transfusion Dependence by Week 24 by Baseline Spleen Volume

Double-Blind Phase

ITT-Anemic Analysis Set

	<Median (1837.09 cm^3)		>=Median (1837.09 cm^3)		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
RBC Transfusion Dependent Rate by Week 24					
Not-Dependent, n(%)	22 (46.8%)	6 (14.0%)	12 (30.8%)	14 (27.5%)	
Dependent, n(%)	25 (53.2%)	37 (86.0%)	27 (69.2%)	37 (72.5%)	
95% Exact CI	0.3808, 0.6789	0.7207, 0.9470	0.5243, 0.8298	0.5826, 0.8411	
Proportion Difference - Stratified CMH Method (95% CI)	-0.38 (-0.57, -0.18)		-0.09 (-0.31, 0.12)		
p-value	<0.001		0.39		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.33 (-0.51, -0.15)		-0.03 (-0.23, 0.16)		
p-value	<0.001		0.74		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.33 (-0.51, -0.12)		-0.03 (-0.24, 0.18)		
p-value	0.001		0.82		
Unadjusted Relative Risk (95% CI)	0.62 (0.46, 0.83)		0.95 (0.73, 1.25)		
p-value [1]	0.001		0.73		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.032
Unadjusted Odds Ratio (95% CI)	0.18 (0.07, 0.52)		0.85 (0.34, 2.13)		
p-value [1]	0.001		0.73		
Unadjusted Absolute Risk Difference (95% CI)	-0.33 (-0.50, -0.15)		-0.03 (-0.22, 0.16)		
Adjusted Relative Risk (95% CI) [2]	0.57 (0.42, 0.76)		0.88 (0.67, 1.15)		
p-value [2]	<0.001		0.34		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.044

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel; RBC = Red Blood Cell

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

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Table 2.3909: Analysis of Rate of RBC Transfusion Dependence by Week 24 by Baseline TSS

Double-Blind Phase

ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
RBC Transfusion Dependent Rate by Week 24					
Not-Dependent, n(%)	18 (40.9%)	13 (23.6%)	15 (36.6%)	7 (18.4%)	
Dependent, n(%)	26 (59.1%)	42 (76.4%)	26 (63.4%)	31 (81.6%)	
95% Exact CI	0.4325, 0.7366	0.6298, 0.8677	0.4694, 0.7788	0.6567, 0.9226	
Proportion Difference - Stratified CMH Method (95% CI)	-0.21 (-0.40, -0.03)		-0.21 (-0.40, -0.01)		
p-value	0.020		0.037		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.17 (-0.36, 0.01)		-0.18 (-0.38, 0.01)		
p-value	0.069		0.070		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.17 (-0.36, 0.03)		-0.18 (-0.39, 0.04)		
p-value	0.082		0.084		
Unadjusted Relative Risk (95% CI)	0.77 (0.58, 1.03)		0.78 (0.59, 1.03)		
p-value [1]	0.079		0.075		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.98
Unadjusted Odds Ratio (95% CI)	0.45 (0.19, 1.06)		0.39 (0.14, 1.10)		
p-value [1]	0.068		0.076		
Unadjusted Absolute Risk Difference (95% CI)	-0.17 (-0.36, 0.01)		-0.18 (-0.37, 0.01)		
Adjusted Relative Risk (95% CI) [2]	0.73 (0.55, 0.96)		0.75 (0.58, 0.97)		
p-value [2]	0.023		0.027		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.81

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel; RBC = Red Blood Cell

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

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Table 2.3901: Analysis of Rate of RBC Transfusion Dependence by Week 24
Double-Blind Phase
ITT-Anemic Analysis Set

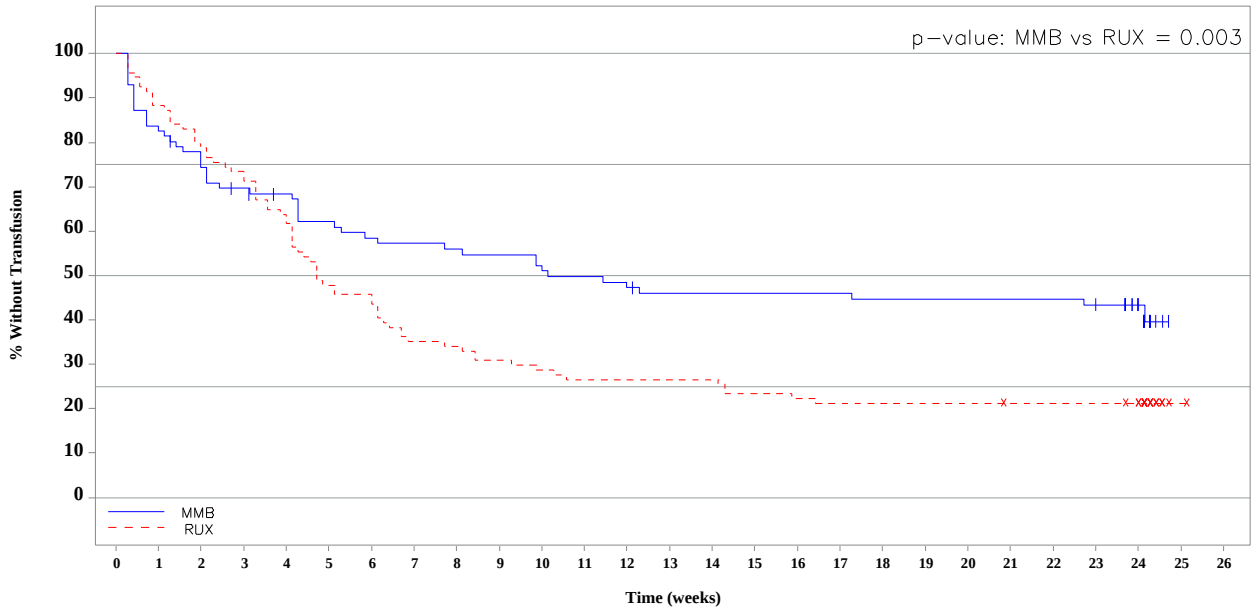
	MMB (N=86)	RUX (N=94)	Total (N=180)
RBC Transfusion Dependent Rate by Week 24			
Not-Dependent, n(%)	34 (39.5%)	20 (21.3%)	54 (30.0%)
Dependent, n(%)	52 (60.5%)	74 (78.7%)	126 (70.0%)
95% Exact CI	0.4934, 0.7085	0.6907, 0.8649	0.6274, 0.7659
Proportion Difference - Stratified CMH Method (95% CI)	-0.22 (-0.35, -0.09)		
p-value	0.001		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.18 (-0.32, -0.05)		
p-value	0.007		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.18 (-0.32, -0.04)		
p-value	0.009		
Unadjusted Relative Risk (95% CI)	0.77 (0.63, 0.94)		
p-value [1]	0.010		
Unadjusted Odds Ratio (95% CI)	0.41 (0.21, 0.80)		
p-value [1]	0.008		
Unadjusted Absolute Risk Difference (95% CI)	-0.18 (-0.31, -0.05)		
Adjusted Relative Risk (95% CI) [2]	0.73 (0.60, 0.88)		
p-value [2]	0.001		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.

Data Extracted: CRF data: 01JUL2019

1.6.4 Sonstige

Figure 2.2801: Kaplan-Meier Plot of Time to First Unit of Any Type Transfused
Double-blind Phase
ITT-Anemic Analysis Set



N at Risk (Events)

MMB	86 (0)	72 (15)	66 (22)	58 (26)	55 (27)	50 (32)	47 (35)	46 (36)	45 (37)	44 (38)	42 (41)	40 (42)	39 (44)	36 (45)	36 (45)	36 (45)	36 (45)	36 (45)	35 (46)	35 (46)	35 (46)	35 (46)	35 (46)	34 (47)	26 (47)	0 (49)	0 (49)
RUX	94 (0)	83 (11)	75 (20)	69 (27)	60 (36)	45 (49)	43 (53)	33 (61)	32 (62)	29 (65)	27 (67)	25 (69)	25 (69)	25 (69)	22 (72)	21 (73)	20 (74)	20 (74)	20 (74)	20 (74)	19 (74)	19 (74)	19 (74)	18 (74)	1 (74)	0 (74)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L).

Data Extracted: CRF data: 01JUL2019
Source: g-tte-any-tran.sas V.03.05 Output file: g-tte-any-tran.pdf 29AUG2023:15:21

Table 2.1612: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
All Strata Combined			
RBC transfusion Rate in DB phase (units/month)			
N	61	53	114
Mean (SD)	1.5 (1.78)	2.5 (2.29)	2.0 (2.09)
Median	0.9	1.8	1.4
Q1, Q3	0.2, 2.5	0.7, 4.1	0.4, 3.3
Min, Max	0.0, 9.1	0.0, 8.2	0.0, 9.1
Negative Binomial Model			
Adjusted for Strata			
Rate of RBC transfusion with 95% CI (units/month)	1.24 (0.83, 1.84)	2.06 (1.36, 3.10)	
Ratio of Rate for RBC Transfusion with 95% CI	0.60 (0.39, 0.93)		
p-value	0.023		
Unadjusted for Strata			
Rate of RBC transfusion with 95% CI (units/month)	1.51 (1.11, 2.06)	2.52 (1.82, 3.47)	
Ratio of Rate for RBC Transfusion with 95% CI	0.60 (0.38, 0.94)		
p-value	0.026		
Proportional Means Model - Supportive Analysis			
Stratified			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.62 (0.42, 0.91)		
p-value	0.015		
Unstratified			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.62 (0.42, 0.91)		
p-value	0.016		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019

Table 2.1612: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
Total number of RBC transfusion unit in DB phase			
N	61	53	114
Mean (SD)	7.4 (9.45)	12.8 (11.27)	9.9 (10.63)
Median	4.0	10.0	6.0
Q1, Q3	1.0, 12.0	4.0, 20.0	2.0, 15.0
Min, Max	0.0, 47.0	0.0, 44.0	0.0, 47.0
Duration of the DB phase (months)			
N	61	53	114
Mean (SD)	5.01 (1.400)	5.31 (0.704)	5.15 (1.137)
Median	5.55	5.52	5.55
Q1, Q3	5.49, 5.59	5.45, 5.59	5.45, 5.59
Min, Max	0.30, 5.72	2.56, 5.78	0.30, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019

Table 2.1612: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
Stratum 1			
Transfusion Dependence at Baseline = 'Yes' and Platelet Count < 100*10E9/L			
RBC transfusion Rate in DB phase (units/month)			
N	10	9	19
Mean (SD)	1.8 (1.60)	3.7 (3.12)	2.7 (2.55)
Median	1.5	3.5	3.2
Q1, Q3	0.4, 3.3	0.4, 5.2	0.4, 4.3
Min, Max	0.0, 4.3	0.0, 8.2	0.0, 8.2
Negative Binomial Model			
Rate of RBC transfusion with 95% CI (units/month)	1.82 (0.90, 3.68)	3.67 (1.78, 7.58)	
Ratio of Rate for RBC Transfusion with 95% CI	0.50 (0.18, 1.36)		
Proportional Means Model - Supportive Analysis			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.52 (0.24, 1.13)		
Total number of RBC transfusion in stratum 1 in DB phase			
N	10	9	19
Mean (SD)	9.0 (8.49)	16.7 (14.14)	12.6 (11.85)
Median	6.5	18.0	9.0
Q1, Q3	2.0, 18.0	2.0, 27.0	2.0, 24.0
Min, Max	0.0, 24.0	0.0, 38.0	0.0, 38.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019

Table 2.1612: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
Duration of the DB phase (months) in stratum 1			
N	10	9	19
Mean (SD)	5.18 (1.174)	4.88 (1.129)	5.04 (1.131)
Median	5.55	5.52	5.55
Q1, Q3	5.49, 5.59	4.63, 5.55	5.49, 5.59
Min, Max	1.84, 5.62	2.56, 5.62	1.84, 5.62

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Table 2.1612: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
Stratum 2			
Transfusion Dependence at Baseline = 'Yes' and Platelet Count >= 100*10E9/L and <= 200*10E9/L			
RBC transfusion Rate in DB phase (units/month)			
N	**20**	**18**	**38**
Mean (SD)	**1.9 (2.46)**	**2.3 (2.29)**	**2.1 (2.36)**
Median	**1.2**	**1.3**	**1.2**
Q1, Q3	**0.0, 2.7**	**0.7, 4.1**	**0.4, 3.6**
Min, Max	**0.0, 9.1**	**0.0, 6.9**	**0.0, 9.1**
Negative Binomial Model			
Rate of RBC transfusion with 95% CI (units/month)	**1.88 (1.04, 3.41)**	**2.26 (1.22, 4.18)**	
Ratio of Rate for RBC Transfusion with 95% CI	**0.83 (0.35, 1.96)**		
Proportional Means Model - Supportive Analysis			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	**0.90 (0.41, 1.94)**		
Total number of RBC transfusion in stratum 2 in DB phase			
N	**20**	**18**	**38**
Mean (SD)	**8.9 (13.18)**	**10.8 (10.59)**	**9.8 (11.90)**
Median	**3.5**	**7.0**	**4.0**
Q1, Q3	**0.0, 7.5**	**4.0, 19.0**	**2.0, 13.0**
Min, Max	**0.0, 47.0**	**0.0, 38.0**	**0.0, 47.0**

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019

Table 2.1612: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
Duration of the DB phase (months) in stratum 2			
N	20	18	38
Mean (SD)	4.75 (1.732)	5.18 (0.834)	4.95 (1.381)
Median	5.55	5.50	5.55
Q1, Q3	5.34, 5.59	5.36, 5.55	5.36, 5.59
Min, Max	0.53, 5.65	2.76, 5.68	0.53, 5.68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019

Table 2.1612: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
Stratum 3			
Transfusion Dependence at Baseline = 'Yes' and Platelet Count > 200*10E9/L			
RBC transfusion Rate in DB phase (units/month)			
N	19	16	35
Mean (SD)	1.4 (1.22)	2.8 (2.10)	2.0 (1.81)
Median	0.9	2.6	1.8
Q1, Q3	0.4, 2.5	1.2, 4.2	0.4, 2.9
Min, Max	0.0, 3.6	0.0, 7.8	0.0, 7.8
Negative Binomial Model			
Rate of RBC transfusion with 95% CI (units/month)	1.40 (0.91, 2.15)	2.82 (1.81, 4.38)	
Ratio of Rate for RBC Transfusion with 95% CI	0.50 (0.27, 0.92)		
Proportional Means Model - Supportive Analysis			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.50 (0.29, 0.85)		
Total number of RBC transfusion in stratum 3 in DB phase			
N	19	16	35
Mean (SD)	6.9 (6.84)	15.7 (11.84)	10.9 (10.31)
Median	4.0	14.0	8.0
Q1, Q3	2.0, 14.0	6.5, 24.0	2.0, 16.0
Min, Max	0.0, 20.0	0.0, 44.0	0.0, 44.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019

Table 2.1612: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
Duration of the DB phase (months) in stratum 3			
N	19	16	35
Mean (SD)	4.94 (1.553)	5.55 (0.101)	5.22 (1.174)
Median	5.55	5.55	5.55
Q1, Q3	5.52, 5.59	5.50, 5.59	5.52, 5.59
Min, Max	0.30, 5.65	5.32, 5.78	0.30, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019

Table 2.1612: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
Stratum 4			
Transfusion Dependence at Baseline = 'No' and Platelet Count < 100*10E9/L			
RBC transfusion Rate in DB phase (units/month)			
N	2	1	3
Mean (SD)	1.3 (1.88)	1.6	1.4 (1.34)
Median	1.3	1.6	1.6
Q1, Q3	0.0, 2.7	1.6, 1.6	0.0, 2.7
Min, Max	0.0, 2.7	1.6, 1.6	0.0, 2.7
Negative Binomial Model			
Rate of RBC transfusion with 95% CI (units/month)	1.33 (0.21, 8.32)	1.62 (0.12, 21.34)	
Ratio of Rate for RBC Transfusion with 95% CI	0.82 (0.03, 19.38)		
Proportional Means Model - Supportive Analysis			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.83 (0.21, 3.33)		
Total number of RBC transfusion in stratum 4 in DB phase			
N	2	1	3
Mean (SD)	7.5 (10.61)	9.0	8.0 (7.55)
Median	7.5	9.0	9.0
Q1, Q3	0.0, 15.0	9.0, 9.0	0.0, 15.0
Min, Max	0.0, 15.0	9.0, 9.0	0.0, 15.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019

Table 2.1612: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
Duration of the DB phase (months) in stratum 4			
N	2	1	3
Mean (SD)	5.60 (0.070)	5.55	5.59 (0.057)
Median	5.60	5.55	5.55
Q1, Q3	5.55, 5.65	5.55, 5.55	5.55, 5.65
Min, Max	5.55, 5.65	5.55, 5.55	5.55, 5.65

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019

Table 2.1612: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
Stratum 5			
Transfusion Dependence at Baseline = 'No' and Platelet Count >= 100*10E9/L and <= 200*10E9/L			
RBC transfusion Rate in DB phase (units/month)			
N	2	2	4
Mean (SD)	0.6 (0.78)	1.3 (1.08)	0.9 (0.89)
Median	0.6	1.3	0.8
Q1, Q3	0.0, 1.1	0.6, 2.1	0.3, 1.6
Min, Max	0.0, 1.1	0.6, 2.1	0.0, 2.1
Negative Binomial Model			
Rate of RBC transfusion with 95% CI (units/month)	0.55 (0.14, 2.14)	1.32 (0.39, 4.40)	
Ratio of Rate for RBC Transfusion with 95% CI	0.42 (0.07, 2.58)		
Proportional Means Model - Supportive Analysis			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.40 (0.08, 2.01)		
Total number of RBC transfusion in stratum 5 in DB phase			
N	2	2	4
Mean (SD)	3.0 (4.24)	7.5 (6.36)	5.3 (5.12)
Median	3.0	7.5	4.5
Q1, Q3	0.0, 6.0	3.0, 12.0	1.5, 9.0
Min, Max	0.0, 6.0	3.0, 12.0	0.0, 12.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019

Table 2.1612: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
Duration of the DB phase (months) in stratum 5			
N	2	2	4
Mean (SD)	5.44 (0.023)	5.62 (0.232)	5.53 (0.170)
Median	5.44	5.62	5.45
Q1, Q3	5.42, 5.45	5.45, 5.78	5.44, 5.62
Min, Max	5.42, 5.45	5.45, 5.78	5.42, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019

Table 2.1612: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
Stratum 6			
Transfusion Dependence at Baseline = 'No' and Platelet Count > 200*10E9/L			
RBC transfusion Rate in DB phase (units/month)			
N	8	7	15
Mean (SD)	0.9 (1.21)	1.5 (1.48)	1.2 (1.33)
Median	0.3	1.5	0.5
Q1, Q3	0.0, 1.7	0.0, 2.7	0.0, 2.5
Min, Max	0.0, 3.0	0.0, 4.0	0.0, 4.0
Negative Binomial Model			
Rate of RBC transfusion with 95% CI (units/month)	0.85 (0.30, 2.43)	1.50 (0.50, 4.47)	
Ratio of Rate for RBC Transfusion with 95% CI	0.57 (0.13, 2.58)		
Proportional Means Model - Supportive Analysis			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.53 (0.17, 1.66)		
Total number of RBC transfusion in stratum 6 in DB phase			
N	8	7	15
Mean (SD)	4.4 (6.09)	8.3 (8.18)	6.2 (7.16)
Median	1.5	8.0	3.0
Q1, Q3	0.0, 9.0	0.0, 15.0	0.0, 14.0
Min, Max	0.0, 14.0	0.0, 22.0	0.0, 22.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019

Table 2.1612: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	RUX (N=53)	Total (N=114)
Duration of the DB phase (months) in stratum 6			
N	8	7	15
Mean (SD)	5.34 (0.398)	5.55 (0.061)	5.44 (0.303)
Median	5.54	5.59	5.55
Q1, Q3	5.04, 5.60	5.49, 5.59	5.45, 5.59
Min, Max	4.67, 5.72	5.45, 5.62	4.67, 5.72

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Table 2.1611: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=25)	RUX (N=41)	Total (N=66)
All Strata Combined			
RBC transfusion Rate in DB phase (units/month)			
N	25	41	66
Mean (SD)	0.3 (1.35)	0.9 (1.04)	0.7 (1.20)
Median	0.0	0.7	0.0
Q1, Q3	0.0, 0.0	0.0, 1.5	0.0, 1.1
Min, Max	0.0, 6.8	0.0, 4.3	0.0, 6.8
Negative Binomial Model			
Adjusted for Strata			
Rate of RBC transfusion with 95% CI (units/month)	0.04 (0.01, 0.12)	0.93 (0.52, 1.67)	
Ratio of Rate for RBC Transfusion with 95% CI	0.04 (0.01, 0.13)		
p-value	< 0.001		
Unadjusted for Strata			
Rate of RBC transfusion with 95% CI (units/month)	0.04 (0.01, 0.12)	0.95 (0.62, 1.45)	
Ratio of Rate for RBC Transfusion with 95% CI	0.04 (0.01, 0.14)		
p-value	< 0.001		
Proportional Means Model - Supportive Analysis			
Stratified			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.03 (0.01, 0.12)		
p-value	< 0.001		
Unstratified			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.04 (0.01, 0.12)		
p-value	< 0.001		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019

Table 2.1611: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=25)	RUX (N=41)	Total (N=66)
Total number of RBC transfusion unit in DB phase			
N	25	41	66
Mean (SD)	0.2 (0.47)	5.3 (5.82)	3.3 (5.22)
Median	0.0	4.0	0.0
Q1, Q3	0.0, 0.0	0.0, 8.0	0.0, 6.0
Min, Max	0.0, 2.0	0.0, 24.0	0.0, 24.0
Duration of the DB phase (months)			
N	25	41	66
Mean (SD)	4.84 (1.711)	5.56 (0.159)	5.29 (1.105)
Median	5.55	5.55	5.55
Q1, Q3	5.45, 5.55	5.52, 5.62	5.52, 5.59
Min, Max	0.30, 5.78	4.80, 5.78	0.30, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-rbc24.sas V.03.05 Output file: t-rbc24-ti.pdf 29AUG2023: 9:00

Table 2.1611: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=25)	RUX (N=41)	Total (N=66)
Stratum 4			
Transfusion Dependence at Baseline = 'No' and Platelet Count < 100*10E9/L			
RBC transfusion Rate in DB phase (units/month)			
N	1	3	4
Mean (SD)	0.0	0.9 (1.09)	0.7 (0.99)
Median	0.0	0.6	0.3
Q1, Q3	0.0, 0.0	0.0, 2.1	0.0, 1.3
Min, Max	0.0, 0.0	0.0, 2.1	0.0, 2.1
Negative Binomial Model			
Rate of RBC transfusion with 95% CI (units/month)	0.00 (0.00, NR)	0.89 (0.21, 3.85)	
Ratio of Rate for RBC Transfusion with 95% CI	0.00 (0.00, NR)		
Proportional Means Model - Supportive Analysis			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.00 (0.00, 0.00)		
Total number of RBC transfusion in stratum 4 in DB phase			
N	1	3	4
Mean (SD)	0.0	5.0 (6.24)	3.8 (5.68)
Median	0.0	3.0	1.5
Q1, Q3	0.0, 0.0	0.0, 12.0	0.0, 7.5
Min, Max	0.0, 0.0	0.0, 12.0	0.0, 12.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Table 2.1611: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=25)	RUX (N=41)	Total (N=66)
Duration of the DB phase (months) in stratum 4			
N	1	3	4
Mean (SD)	5.59	5.32 (0.474)	5.39 (0.409)
Median	5.59	5.45	5.52
Q1, Q3	5.59, 5.59	4.80, 5.72	5.13, 5.65
Min, Max	5.59, 5.59	4.80, 5.72	4.80, 5.72

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-rbc24.sas V.03.05 Output file: t-rbc24-ti.pdf 29AUG2023: 9:00

Table 2.1611: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=25)	RUX (N=41)	Total (N=66)
Stratum 5			
Transfusion Dependence at Baseline = 'No' and Platelet Count >= 100*10E9/L and <= 200*10E9/L			
RBC transfusion Rate in DB phase (units/month)			
N	**14**	**14**	**28**
Mean (SD)	**0.5 (1.80)**	**1.0 (0.98)**	**0.8 (1.45)**
Median	**0.0**	**0.9**	**0.0**
Q1, Q3	**0.0, 0.0**	**0.2, 1.8**	**0.0, 1.1**
Min, Max	**0.0, 6.8**	**0.0, 3.2**	**0.0, 6.8**
Negative Binomial Model			
Rate of RBC transfusion with 95% CI (units/month)	**0.05 (0.01, 0.20)**	**1.04 (0.56, 1.95)**	
Ratio of Rate for RBC Transfusion with 95% CI	**0.05 (0.01, 0.22)**		
Proportional Means Model - Supportive Analysis			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	**0.04 (0.01, 0.20)**		
Total number of RBC transfusion in stratum 5 in DB phase			
N	**14**	**14**	**28**
Mean (SD)	**0.2 (0.58)**	**5.8 (5.42)**	**3.0 (4.73)**
Median	**0.0**	**5.0**	**0.0**
Q1, Q3	**0.0, 0.0**	**1.0, 10.0**	**0.0, 5.0**
Min, Max	**0.0, 2.0**	**0.0, 18.0**	**0.0, 18.0**

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019

Table 2.1611: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=25)	RUX (N=41)	Total (N=66)
Duration of the DB phase (months) in stratum 5			
N	14	14	28
Mean (SD)	4.97 (1.531)	5.56 (0.088)	5.26 (1.107)
Median	5.54	5.55	5.55
Q1, Q3	5.45, 5.55	5.52, 5.59	5.50, 5.59
Min, Max	0.30, 5.62	5.39, 5.78	0.30, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Table 2.1611: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=25)	RUX (N=41)	Total (N=66)
Stratum 6			
Transfusion Dependence at Baseline = 'No' and Platelet Count > 200*10E9/L			
RBC transfusion Rate in DB phase (units/month)			
N	10	24	34
Mean (SD)	0.0 (0.05)	0.9 (1.11)	0.6 (1.01)
Median	0.0	0.6	0.0
Q1, Q3	0.0, 0.0	0.0, 1.3	0.0, 1.1
Min, Max	0.0, 0.2	0.0, 4.3	0.0, 4.3
Negative Binomial Model			
Rate of RBC transfusion with 95% CI (units/month)	0.02 (0.00, 0.19)	0.90 (0.49, 1.65)	
Ratio of Rate for RBC Transfusion with 95% CI	0.02 (0.00, 0.23)		
Proportional Means Model - Supportive Analysis			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.02 (0.00, 0.16)		
Total number of RBC transfusion in stratum 6 in DB phase			
N	10	24	34
Mean (SD)	0.1 (0.32)	5.0 (6.22)	3.6 (5.67)
Median	0.0	3.5	0.0
Q1, Q3	0.0, 0.0	0.0, 7.5	0.0, 6.0
Min, Max	0.0, 1.0	0.0, 24.0	0.0, 24.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019

Table 2.1611: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=25)	RUX (N=41)	Total (N=66)
Duration of the DB phase (months) in stratum 6			
N	10	24	34
Mean (SD)	4.59 (2.067)	5.59 (0.109)	5.30 (1.178)
Median	5.54	5.55	5.55
Q1, Q3	5.45, 5.55	5.54, 5.65	5.52, 5.65
Min, Max	0.62, 5.78	5.36, 5.78	0.62, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-rbc24.sas V.03.05 Output file: t-rbc24-ti.pdf 29AUG2023: 9:00

Table 2.1602: Analysis of Rate of RBC Transfusion by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
RBC transfusion Rate in DB phase (units/month)					
N	24	36	62	58	
Mean (SD)	0.6 (0.83)	1.4 (1.95)	1.4 (1.96)	2.1 (2.00)	
Median	0.1	0.7	0.4	1.8	
Q1, Q3	0.0, 1.2	0.0, 1.5	0.0, 2.5	0.6, 3.2	
Min, Max	0.0, 2.7	0.0, 7.8	0.0, 9.1	0.0, 8.2	
Negative Binomial Model					
Adjusted for Strata					
Rate of RBC transfusion with 95% CI (units/month)	0.50 (0.26, 0.95)	1.35 (0.75, 2.41)	0.88 (0.59, 1.32)	2.17 (1.51, 3.11)	
Ratio of Rate for RBC Transfusion with 95% CI	0.37 (0.15, 0.89)	-	0.41 (0.25, 0.67)	-	
p-value	0.027	-	< 0.001	-	
Adjusted interaction test for Treatment*Age Group [1]	-	-	-	-	0.91
Unadjusted for Strata					
Rate of RBC transfusion with 95% CI (units/month)	0.63 (0.32, 1.25)	1.35 (0.79, 2.32)	1.32 (0.92, 1.89)	2.13 (1.49, 3.04)	
Ratio of Rate for RBC Transfusion with 95% CI	0.47 (0.20, 1.12)	-	0.62 (0.37, 1.03)	-	
p-value	0.088	-	0.062	-	
Unadjusted interaction test for Treatment*Age Group [1]	-	-	-	-	0.56

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-db-csr.sas V.03.05 Output file: t-rbc-db-csr-age.pdf 29AUG2023: 9:44

Table 2.1602: Analysis of Rate of RBC Transfusion by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Proportional Means Model - Supportive Analysis					
Stratified					
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.45 (0.25, 0.81)	-	0.50 (0.33, 0.75)	-	
p-value	0.008	-	< 0.001	-	
Unstratified					
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.50 (0.25, 1.00)	-	0.61 (0.39, 0.96)	-	
p-value	0.051	-	0.033	-	
Total number of RBC transfusion unit in DB phase					
N	24	36	62	58	
Mean (SD)	3.3 (4.50)	6.7 (9.12)	6.1 (9.67)	11.3 (10.15)	
Median	0.5	4.0	2.0	10.0	
Q1, Q3	0.0, 5.5	0.0, 8.0	0.0, 7.0	3.0, 16.0	
Min, Max	0.0, 15.0	0.0, 38.0	0.0, 47.0	0.0, 44.0	
Duration of the DB phase (months)					
N	24	36	62	58	
Mean (SD)	5.23 (1.037)	5.37 (0.614)	4.85 (1.625)	5.45 (0.511)	
Median	5.55	5.52	5.55	5.55	
Q1, Q3	5.50, 5.59	5.49, 5.57	5.45, 5.59	5.52, 5.62	
Min, Max	1.22, 5.78	2.56, 5.75	0.30, 5.72	2.76, 5.78	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-db-csr.sas V.03.05 Output file: t-rbc-db-csr-age.pdf 29AUG2023: 9:44

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Table 2.1607: Analysis of Rate of RBC Transfusion by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8g/dL		HGB >=8g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
RBC transfusion Rate in DB phase (units/month)					
N	28	21	58	73	
Mean (SD)	1.6 (1.96)	2.8 (2.58)	1.0 (1.62)	1.6 (1.73)	
Median	1.2	2.2	0.0	0.9	
Q1, Q3	0.3, 2.3	0.7, 5.0	0.0, 1.6	0.2, 2.2	
Min, Max	0.0, 9.1	0.0, 8.2	0.0, 6.8	0.0, 7.8	
Negative Binomial Model					
Adjusted for Strata					
Rate of RBC transfusion with 95% CI (units/month)	1.57 (1.00, 2.46)	2.90 (1.78, 4.72)	0.82 (0.53, 1.25)	1.95 (1.30, 2.93)	
Ratio of Rate for RBC Transfusion with 95% CI	0.54 (0.28, 1.05)	-	0.42 (0.24, 0.73)	-	
p-value	0.068	-	0.002	-	
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [1]	-	-	-	-	0.55
Unadjusted for Strata					
Rate of RBC transfusion with 95% CI (units/month)	1.57 (1.01, 2.42)	2.82 (1.74, 4.56)	0.91 (0.59, 1.41)	1.55 (1.07, 2.25)	
Ratio of Rate for RBC Transfusion with 95% CI	0.56 (0.29, 1.07)	-	0.59 (0.33, 1.04)	-	
p-value	0.077	-	0.069	-	
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [1]	-	-	-	-	0.91

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-db-csr.sas V.03.05 Output file: t-rbc-db-csr-hgb.pdf 29AUG2023: 9:45

Table 2.1607: Analysis of Rate of RBC Transfusion by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8g/dL		HGB >=8g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Proportional Means Model - Supportive Analysis					
Stratified					
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.57 (0.31, 1.05)	-	0.52 (0.33, 0.83)	-	
p-value	0.069	-	0.006	-	
Unstratified					
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.57 (0.31, 1.07)	-	0.58 (0.35, 0.97)	-	
p-value	0.080	-	0.038	-	
Total number of RBC transfusion unit in DB phase					
N	28	21	58	73	
Mean (SD)	7.3 (9.98)	13.9 (12.72)	4.4 (7.80)	8.2 (8.73)	
Median	3.5	10.0	0.0	5.0	
Q1, Q3	1.5, 9.0	4.0, 19.0	0.0, 5.0	1.0, 12.0	
Min, Max	0.0, 47.0	0.0, 44.0	0.0, 36.0	0.0, 38.0	
Duration of the DB phase (months)					
N	28	21	58	73	
Mean (SD)	4.75 (1.760)	5.21 (0.875)	5.06 (1.344)	5.48 (0.403)	
Median	5.55	5.52	5.55	5.55	
Q1, Q3	5.47, 5.59	5.45, 5.55	5.45, 5.59	5.52, 5.59	
Min, Max	0.30, 5.65	2.56, 5.68	0.30, 5.78	3.19, 5.78	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-db-csr.sas V.03.05 Output file: t-rbc-db-csr-hgb.pdf 29AUG2023: 9:45

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Table 2.1606: Analysis of Rate of RBC Transfusion by Baseline IPSS Two-Level Risk

Double-Blind Phase

ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
RBC transfusion Rate in DB phase (units/month)					
N	28	24	58	70	
Mean (SD)	0.6 (0.97)	1.7 (2.15)	1.4 (1.98)	1.9 (1.97)	
Median	0.0	1.1	0.4	1.2	
Q1, Q3	0.0, 1.2	0.0, 2.3	0.0, 2.5	0.4, 2.8	
Min, Max	0.0, 3.3	0.0, 7.8	0.0, 9.1	0.0, 8.2	
Negative Binomial Model					
Adjusted for Strata					
Rate of RBC transfusion with 95% CI (units/month)	0.54 (0.29, 1.01)	1.74 (0.91, 3.34)	0.75 (0.45, 1.23)	1.43 (0.93, 2.20)	
Ratio of Rate for RBC Transfusion with 95% CI	0.31 (0.13, 0.77)	-	0.52 (0.32, 0.84)	-	
p-value	0.011	-	0.008	-	
Adjusted interaction test for Treatment*IPSS 2-Level Risk [1]	-	-	-	-	0.30
Unadjusted for Strata					
Rate of RBC transfusion with 95% CI (units/month)	0.64 (0.33, 1.25)	1.71 (0.86, 3.40)	1.36 (0.93, 1.97)	1.87 (1.35, 2.60)	
Ratio of Rate for RBC Transfusion with 95% CI	0.38 (0.14, 0.97)	-	0.72 (0.44, 1.19)	-	
p-value	0.044	-	0.20	-	
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [1]	-	-	-	-	0.19

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Proportional means model is Andersen-Gill model with robust sandwich variance estimate.

[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

RBC = Red Blood Cell.

Data Extracted: CRF data: 01JUL2019

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Table 2.1606: Analysis of Rate of RBC Transfusion by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Proportional Means Model - Supportive Analysis					
Stratified					
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.36 (0.18, 0.73)	-	0.64 (0.42, 0.97)	-	
p-value	0.005	-	0.037	-	
Unstratified					
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.42 (0.20, 0.89)	-	0.71 (0.45, 1.12)	-	
p-value	0.023	-	0.14	-	
Total number of RBC transfusion unit in DB phase					
N	28	24	58	70	
Mean (SD)	3.3 (5.32)	8.5 (10.01)	6.3 (9.71)	9.9 (10.01)	
Median	0.0	6.0	2.0	6.5	
Q1, Q3	0.0, 4.5	0.0, 11.0	0.0, 7.0	2.0, 15.0	
Min, Max	0.0, 18.0	0.0, 38.0	0.0, 47.0	0.0, 44.0	
Duration of the DB phase (months)					
N	28	24	58	70	
Mean (SD)	5.05 (1.469)	5.34 (0.737)	4.91 (1.509)	5.45 (0.474)	
Median	5.55	5.54	5.55	5.55	
Q1, Q3	5.50, 5.59	5.49, 5.60	5.45, 5.59	5.49, 5.59	
Min, Max	0.62, 5.65	2.56, 5.78	0.30, 5.78	2.76, 5.78	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-db-csr.sas V.03.05 Output file: t-rbc-db-csr-ip2.pdf 29AUG2023: 9:45

Table 2.1605: Analysis of Rate of RBC Transfusion by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
RBC transfusion Rate in DB phase (units/month)				
N	2	4	26	20
Mean (SD)	0.0 (0.00)	1.0 (0.74)	0.7 (0.99)	1.9 (2.31)
Median	0.0	1.1	0.0	1.1
Q1, Q3	0.0, 0.0	0.4, 1.5	0.0, 1.4	0.0, 2.8
Min, Max	0.0, 0.0	0.0, 1.6	0.0, 3.3	0.0, 7.8
Negative Binomial Model				
Adjusted for Strata				
Rate of RBC transfusion with 95% CI (units/month)	NA	NA	NA	NA
Ratio of Rate for RBC Transfusion with 95% CI	NA	-	NA	-
p-value	NA	-	NA	-
Adjusted interaction test for Treatment*IPSS 3-Level Risk [1]	-	-	-	-
Unadjusted for Strata				
Rate of RBC transfusion with 95% CI (units/month)	NA	NA	NA	NA
Ratio of Rate for RBC Transfusion with 95% CI	NA	-	NA	-
p-value	NA	-	NA	-
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [1]	-	-	-	-

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-db-csr.sas V.03.05 Output file: t-rbc-db-csr-ip3.pdf 29AUG2023: 9:45

Table 2.1605: Analysis of Rate of RBC Transfusion by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=58)	High Risk RUX (N=70)	p-value
RBC transfusion Rate in DB phase (units/month)			
N	58	70	
Mean (SD)	1.4 (1.98)	1.9 (1.97)	
Median	0.4	1.2	
Q1, Q3	0.0, 2.5	0.4, 2.8	
Min, Max	0.0, 9.1	0.0, 8.2	
Negative Binomial Model			
Adjusted for Strata			
Rate of RBC transfusion with 95% CI (units/month)	NA	NA	
Ratio of Rate for RBC Transfusion with 95% CI	NA	-	
p-value	NA	-	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [1]	-	-	NA
Unadjusted for Strata			
Rate of RBC transfusion with 95% CI (units/month)	NA	NA	
Ratio of Rate for RBC Transfusion with 95% CI	NA	-	
p-value	NA	-	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [1]	-	-	NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell.

Data Extracted: CRF data: 01JUL2019

Table 2.1605: Analysis of Rate of RBC Transfusion by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Proportional Means Model - Supportive Analysis				
Stratified				
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	NA -		NA -	
p-value	NA	-	NA	-
Unstratified				
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	NA -		NA -	
p-value	NA	-	NA	-
Total number of RBC transfusion unit in DB phase				
N	2	4	26	20
Mean (SD)	0.0 (0.00)	5.3 (4.11)	3.5 (5.44)	9.1 (10.77)
Median	0.0	6.0	0.0	6.0
Q1, Q3	0.0, 0.0	2.0, 8.5	0.0, 5.0	0.0, 13.0
Min, Max	0.0, 0.0	0.0, 9.0	0.0, 18.0	0.0, 38.0
Duration of the DB phase (months)				
N	2	4	26	20
Mean (SD)	5.50 (0.070)	5.54 (0.056)	5.02 (1.521)	5.30 (0.804)
Median	5.50	5.54	5.55	5.54
Q1, Q3	5.45, 5.55	5.50, 5.59	5.52, 5.59	5.49, 5.60
Min, Max	5.45, 5.55	5.49, 5.62	0.62, 5.65	2.56, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-db-csr.sas V.03.05 Output file: t-rbc-db-csr-ip3.pdf 29AUG2023: 9:45

Table 2.1605: Analysis of Rate of RBC Transfusion by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=58)	High Risk RUX (N=70)	p-value
Proportional Means Model - Supportive Analysis			
Stratified			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	NA	-	
p-value	NA	-	
Unstratified			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	NA	-	
p-value	NA	-	
Total number of RBC transfusion unit in DB phase			
N	58	70	
Mean (SD)	6.3 (9.71)	9.9 (10.01)	
Median	2.0	6.5	
Q1, Q3	0.0, 7.0	2.0, 15.0	
Min, Max	0.0, 47.0	0.0, 44.0	
Duration of the DB phase (months)			
N	58	70	
Mean (SD)	4.91 (1.509)	5.45 (0.474)	
Median	5.55	5.55	
Q1, Q3	5.45, 5.59	5.49, 5.59	
Min, Max	0.30, 5.78	2.76, 5.78	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-db-csr.sas V.03.05 Output file: t-rbc-db-csr-ip3.pdf 29AUG2023: 9:45

Table 2.1608: Analysis of Rate of RBC Transfusion by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
RBC transfusion Rate in DB phase (units/month)				
N	59	54	16	28
Mean (SD)	1.1 (1.83)	1.6 (1.84)	1.5 (1.79)	2.1 (2.17)
Median	0.3	0.7	1.1	1.7
Q1, Q3	0.0, 1.8	0.3, 2.1	0.0, 2.3	0.1, 3.4
Min, Max	0.0, 9.1	0.0, 7.8	0.0, 6.8	0.0, 7.8
Negative Binomial Model				
Adjusted for Strata				
Rate of RBC transfusion with 95% CI (units/month)	0.76 (0.49, 1.17)	1.42 (0.95, 2.10)	1.19 (0.61, 2.31)	3.10 (1.62, 5.93)
Ratio of Rate for RBC Transfusion with 95% CI	0.54 (0.31, 0.94)	-	0.38 (0.16, 0.91)	-
p-value	0.028	-	0.029	-
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [1]	-	-	-	-
Unadjusted for Strata				
Rate of RBC transfusion with 95% CI (units/month)	1.12 (0.74, 1.69)	1.55 (1.02, 2.36)	1.28 (0.63, 2.64)	2.13 (1.28, 3.54)
Ratio of Rate for RBC Transfusion with 95% CI	0.72 (0.40, 1.30)	-	0.60 (0.25, 1.46)	-
p-value	0.27	-	0.26	-
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [1]	-	-	-	-

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-db-csr.sas V.03.05 Output file: t-rbc-db-csr-mf.pdf 29AUG2023: 9:45

Table 2.1608: Analysis of Rate of RBC Transfusion by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=11)	Post-PV Myelofibrosis RUX (N=12)	p-value
RBC transfusion Rate in DB phase (units/month)			
N	11	12	
Mean (SD)	0.9 (1.21)	2.4 (2.28)	
Median	0.0	2.0	
Q1, Q3	0.0, 1.6	1.0, 2.7	
Min, Max	0.0, 3.6	0.0, 8.2	
Negative Binomial Model			
Adjusted for Strata			
Rate of RBC transfusion with 95% CI (units/month)	0.75 (0.27, 2.12)	2.20 (1.13, 4.30)	
Ratio of Rate for RBC Transfusion with 95% CI	0.34 (0.09, 1.32)	-	
p-value	0.12	-	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [1]	-	-	0.34
Unadjusted for Strata			
Rate of RBC transfusion with 95% CI (units/month)	0.88 (0.39, 2.01)	2.40 (1.18, 4.91)	
Ratio of Rate for RBC Transfusion with 95% CI	0.37 (0.12, 1.09)	-	
p-value	0.071	-	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [1]	-	-	0.63

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-db-csr.sas V.03.05 Output file: t-rbc-db-csr-mf.pdf 29AUG2023: 9:45

Table 2.1608: Analysis of Rate of RBC Transfusion by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Proportional Means Model - Supportive Analysis				
Stratified				
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.71 (0.43, 1.19)	-	0.42 (0.27, 0.67)	-
p-value	0.19	-	< 0.001	-
Unstratified				
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.74 (0.44, 1.26)	-	0.55 (0.29, 1.04)	-
p-value	0.27	-	0.065	-
Total number of RBC transfusion unit in DB phase				
N	59	54	16	28
Mean (SD)	5.6 (9.56)	8.1 (9.09)	5.6 (6.09)	10.9 (11.00)
Median	2.0	4.0	4.5	9.0
Q1, Q3	0.0, 7.0	2.0, 12.0	0.0, 8.5	0.5, 17.0
Min, Max	0.0, 47.0	0.0, 38.0	0.0, 19.0	0.0, 44.0
Duration of the DB phase (months)				
N	59	54	16	28
Mean (SD)	5.05 (1.355)	5.45 (0.459)	5.01 (1.503)	5.39 (0.775)
Median	5.55	5.55	5.55	5.55
Q1, Q3	5.45, 5.59	5.49, 5.59	5.50, 5.59	5.52, 5.63
Min, Max	0.53, 5.72	3.19, 5.78	0.30, 5.78	2.56, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-db-csr.sas V.03.05 Output file: t-rbc-db-csr-mf.pdf 29AUG2023: 9:45

Table 2.1608: Analysis of Rate of RBC Transfusion by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=11)	Post-PV Myelofibrosis RUX (N=12)	p-value
Proportional Means Model - Supportive Analysis			
Stratified			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.46 (0.18, 1.19)	-	
p-value	0.11	-	
Unstratified			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.36 (0.12, 1.07)	-	
p-value	0.067	-	
Total number of RBC transfusion unit in DB phase			
N	11	12	
Mean (SD)	3.6 (6.48)	12.6 (10.98)	
Median	0.0	11.0	
Q1, Q3	0.0, 3.0	5.5, 14.5	
Min, Max	0.0, 20.0	0.0, 38.0	
Duration of the DB phase (months)			
N	11	12	
Mean (SD)	4.37 (2.089)	5.40 (0.266)	
Median	5.55	5.47	
Q1, Q3	2.00, 5.59	5.34, 5.55	
Min, Max	0.30, 5.65	4.63, 5.65	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-db-csr.sas V.03.05 Output file: t-rbc-db-csr-mf.pdf 29AUG2023: 9:45

Table 2.1604: Analysis of Rate of RBC Transfusion by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
RBC transfusion Rate in DB phase (units/month)					
N	53	51	33	43	
Mean (SD)	1.5 (2.00)	2.2 (2.13)	0.7 (1.09)	1.4 (1.80)	
Median	0.5	1.6	0.0	0.7	
Q1, Q3	0.0, 2.5	0.4, 3.6	0.0, 1.1	0.0, 1.8	
Min, Max	0.0, 9.1	0.0, 7.8	0.0, 3.4	0.0, 8.2	
Negative Binomial Model					
Adjusted for Strata					
Rate of RBC transfusion with 95% CI (units/month)	0.98 (0.68, 1.43)	2.04 (1.43, 2.91)	0.01 (0.00, Inf.)	0.04 (0.00, Inf.)	
Ratio of Rate for RBC Transfusion with 95% CI	0.48 (0.29, 0.79)	-	0.29 (0.13, 0.64)	-	
p-value	0.004	-	0.002	-	
Adjusted interaction test for Treatment*Region [1]	-	-	-	-	0.26
Unadjusted for Strata					
Rate of RBC transfusion with 95% CI (units/month)	1.41 (0.96, 2.07)	2.17 (1.49, 3.16)	0.66 (0.37, 1.18)	1.44 (0.88, 2.33)	
Ratio of Rate for RBC Transfusion with 95% CI	0.65 (0.38, 1.11)	-	0.46 (0.22, 0.98)	-	
p-value	0.12	-	0.043	-	
Unadjusted interaction test for Treatment*Region [1]	-	-	-	-	0.44

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell. Inf. = Infinite.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-db-csr.sas V.03.05 Output file: t-rbc-db-csr-reg.pdf 29AUG2023: 9:45

Table 2.1604: Analysis of Rate of RBC Transfusion by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Proportional Means Model - Supportive Analysis					
Stratified					
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.53 (0.35, 0.79)	-	0.45 (0.25, 0.82)	-	
p-value	0.002	-	0.009	-	
Unstratified					
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.66 (0.41, 1.05)	-	0.46 (0.24, 0.90)	-	
p-value	0.079	-	0.024	-	
Total number of RBC transfusion unit in DB phase					
N	53	51	33	43	
Mean (SD)	6.7 (9.94)	11.0 (10.43)	3.2 (5.36)	7.7 (9.20)	
Median	2.0	9.0	0.0	4.0	
Q1, Q3	0.0, 7.0	2.0, 18.0	0.0, 6.0	0.0, 10.0	
Min, Max	0.0, 47.0	0.0, 44.0	0.0, 19.0	0.0, 38.0	
Duration of the DB phase (months)					
N	53	51	33	43	
Mean (SD)	4.94 (1.485)	5.36 (0.710)	4.98 (1.518)	5.50 (0.245)	
Median	5.55	5.55	5.55	5.55	
Q1, Q3	5.45, 5.59	5.52, 5.59	5.52, 5.59	5.49, 5.59	
Min, Max	0.30, 5.78	2.56, 5.78	0.62, 5.72	4.63, 5.78	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell. Inf. = Infinite.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-db-csr.sas V.03.05 Output file: t-rbc-db-csr-reg.pdf 29AUG2023: 9:45

Table 2.1603: Analysis of Rate of RBC Transfusion by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
RBC transfusion Rate in DB phase (units/month)					
N	50	56	36	38	
Mean (SD)	1.5 (1.88)	2.2 (2.19)	0.7 (1.45)	1.3 (1.57)	
Median	0.8	1.5	0.0	0.9	
Q1, Q3	0.0, 2.5	0.5, 3.7	0.0, 0.5	0.0, 1.8	
Min, Max	0.0, 9.1	0.0, 8.2	0.0, 6.8	0.0, 7.8	
Negative Binomial Model					
Adjusted for Strata					
Rate of RBC transfusion with 95% CI (units/month)	0.91 (0.57, 1.44)	1.86 (1.24, 2.77)	0.61 (0.32, 1.15)	1.47 (0.81, 2.66)	
Ratio of Rate for RBC Transfusion with 95% CI	0.49 (0.30, 0.80)	-	0.41 (0.17, 1.00)	-	
p-value	0.004	-	0.051	-	
Adjusted interaction test for Treatment*Gender [1]	-	-	-	-	0.46
Unadjusted for Strata					
Rate of RBC transfusion with 95% CI (units/month)	1.46 (1.00, 2.12)	2.19 (1.55, 3.10)	0.61 (0.33, 1.13)	1.31 (0.77, 2.24)	
Ratio of Rate for RBC Transfusion with 95% CI	0.67 (0.40, 1.11)	-	0.47 (0.21, 1.06)	-	
p-value	0.12	-	0.068	-	
Unadjusted interaction test for Treatment*Gender [1]	-	-	-	-	0.42

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-db-csr.sas V.03.05 Output file: t-rbc-db-csr-sex.pdf 29AUG2023: 9:44

Table 2.1603: Analysis of Rate of RBC Transfusion by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Proportional Means Model - Supportive Analysis					
Stratified					
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.57 (0.37, 0.88)	-	0.45 (0.22, 0.89)	-	
p-value	0.011	-	0.022	-	
Unstratified					
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.69 (0.44, 1.08)	-	0.40 (0.19, 0.84)	-	
p-value	0.10	-	0.016	-	
Total number of RBC transfusion unit in DB phase					
N	50	56	36	38	
Mean (SD)	7.5 (10.08)	11.1 (10.56)	2.4 (4.73)	7.2 (8.66)	
Median	3.0	8.0	0.0	5.0	
Q1, Q3	0.0, 12.0	3.0, 18.5	0.0, 2.0	0.0, 10.0	
Min, Max	0.0, 47.0	0.0, 38.0	0.0, 20.0	0.0, 44.0	
Duration of the DB phase (months)					
N	50	56	36	38	
Mean (SD)	5.27 (0.996)	5.36 (0.688)	4.53 (1.915)	5.51 (0.214)	
Median	5.55	5.55	5.54	5.55	
Q1, Q3	5.52, 5.59	5.49, 5.59	4.98, 5.55	5.49, 5.62	
Min, Max	0.53, 5.72	2.56, 5.78	0.30, 5.78	4.67, 5.78	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-db-csr.sas V.03.05 Output file: t-rbc-db-csr-sex.pdf 29AUG2023: 9:44

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Table 2.1610: Analysis of Rate of RBC Transfusion by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
RBC transfusion Rate in DB phase (units/month)					
N	47	43	39	51	
Mean (SD)	1.0 (1.61)	2.0 (1.67)	1.3 (1.91)	1.7 (2.26)	
Median	0.2	1.8	0.4	0.7	
Q1, Q3	0.0, 1.8	0.7, 2.8	0.0, 2.1	0.2, 2.2	
Min, Max	0.0, 6.8	0.0, 7.8	0.0, 9.1	0.0, 8.2	
Negative Binomial Model					
Adjusted for Strata					
Rate of RBC transfusion with 95% CI (units/month)	0.63 (0.38, 1.07)	2.17 (1.34, 3.50)	0.97 (0.59, 1.59)	1.50 (1.00, 2.25)	
Ratio of Rate for RBC Transfusion with 95% CI	0.29 (0.16, 0.55)	-	0.65 (0.35, 1.20)	-	
p-value	< 0.001	-	0.17	-	
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [1]	-	-	-	-	0.046
Unadjusted for Strata					
Rate of RBC transfusion with 95% CI (units/month)	0.94 (0.60, 1.48)	1.95 (1.25, 3.04)	1.33 (0.83, 2.13)	1.73 (1.16, 2.60)	
Ratio of Rate for RBC Transfusion with 95% CI	0.48 (0.25, 0.91)	-	0.77 (0.41, 1.43)	-	
p-value	0.024	-	0.40	-	
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [1]	-	-	-	-	0.30

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-db-csr.sas V.03.05 Output file: t-rbc-db-csr-spv.pdf 29AUG2023: 9:45

GSK Oncology
Study GS-US-352-0101

Table 2.1610: Analysis of Rate of RBC Transfusion by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Proportional Means Model - Supportive Analysis					
Stratified					
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.38 (0.25, 0.60)	-	0.74 (0.42, 1.31)	-	
p-value	< 0.001	-	0.30	-	
Unstratified					
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.45 (0.26, 0.76)	-	0.83 (0.46, 1.48)	-	
p-value	0.003	-	0.53	-	
Total number of RBC transfusion unit in DB phase					
N	47	43	39	51	
Mean (SD)	4.2 (6.96)	10.6 (9.09)	6.7 (10.19)	8.6 (10.67)	
Median	1.0	10.0	2.0	4.0	
Q1, Q3	0.0, 6.0	4.0, 15.0	0.0, 8.0	1.0, 12.0	
Min, Max	0.0, 26.0	0.0, 44.0	0.0, 47.0	0.0, 38.0	
Duration of the DB phase (months)					
N	47	43	39	51	
Mean (SD)	4.91 (1.609)	5.47 (0.416)	5.02 (1.348)	5.38 (0.644)	
Median	5.55	5.55	5.55	5.55	
Q1, Q3	5.49, 5.59	5.49, 5.62	5.45, 5.59	5.49, 5.59	
Min, Max	0.30, 5.78	3.19, 5.78	0.30, 5.72	2.56, 5.78	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-db-csr.sas V.03.05 Output file: t-rbc-db-csr-spv.pdf 29AUG2023: 9:45

Table 2.1609: Analysis of Rate of RBC Transfusion by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
RBC transfusion Rate in DB phase (units/month)					
N	44	55	41	38	
Mean (SD)	1.0 (1.36)	1.7 (1.72)	1.4 (2.10)	1.9 (2.19)	
Median	0.4	1.1	0.2	1.2	
Q1, Q3	0.0, 1.6	0.4, 2.7	0.0, 2.1	0.3, 2.6	
Min, Max	0.0, 4.7	0.0, 8.2	0.0, 9.1	0.0, 7.8	
Negative Binomial Model					
Adjusted for Strata					
Rate of RBC transfusion with 95% CI (units/month)	0.02 (0.00, Inf.)	0.04 (0.00, Inf.)	0.98 (0.62, 1.54)	1.74 (1.13, 2.68)	
Ratio of Rate for RBC Transfusion with 95% CI	0.42 (0.24, 0.74)	-	0.56 (0.30, 1.05)	-	
p-value	0.003	-	0.070	-	
Adjusted interaction test for Treatment*Baseline TSS Group [1]	-	-	-	-	0.21
Unadjusted for Strata					
Rate of RBC transfusion with 95% CI (units/month)	0.95 (0.62, 1.46)	1.68 (1.16, 2.43)	1.34 (0.81, 2.21)	1.90 (1.15, 3.16)	
Ratio of Rate for RBC Transfusion with 95% CI	0.57 (0.32, 1.00)	-	0.70 (0.34, 1.43)	-	
p-value	0.051	-	0.33	-	
Unadjusted interaction test for Treatment*Baseline TSS Group [1]	-	-	-	-	0.65

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell. Inf. = Infinite.

Data Extracted: CRF data: 01JUL2019

Table 2.1609: Analysis of Rate of RBC Transfusion by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Proportional Means Model - Supportive Analysis					
Stratified					
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.52 (0.32, 0.83)	-	0.62 (0.37, 1.05)	-	
p-value	0.006	-	0.078	-	
Unstratified					
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.59 (0.36, 0.96)	-	0.71 (0.38, 1.31)	-	
p-value	0.036	-	0.27	-	
Total number of RBC transfusion unit in DB phase					
N	44	55	41	38	
Mean (SD)	4.9 (7.17)	8.9 (8.85)	5.9 (10.08)	9.6 (10.15)	
Median	2.0	6.0	1.0	6.5	
Q1, Q3	0.0, 7.5	2.0, 14.0	0.0, 7.0	2.0, 14.0	
Min, Max	0.0, 26.0	0.0, 38.0	0.0, 47.0	0.0, 38.0	
Duration of the DB phase (months)					
N	44	55	41	38	
Mean (SD)	5.21 (1.276)	5.44 (0.538)	4.67 (1.671)	5.40 (0.582)	
Median	5.55	5.55	5.55	5.52	
Q1, Q3	5.52, 5.59	5.52, 5.59	4.80, 5.59	5.45, 5.55	
Min, Max	0.30, 5.72	2.56, 5.78	0.30, 5.78	2.76, 5.78	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell. Inf. = Infinite.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbc-db-csr.sas V.03.05 Output file: t-rbc-db-csr-tss.pdf 29AUG2023: 9:45

Table 2.1601: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
All Strata Combined			
RBC transfusion Rate in DB phase (units/month)			
N	86	94	180
Mean (SD)	1.2 (1.75)	1.8 (2.01)	1.5 (1.91)
Median	0.4	1.2	0.7
Q1, Q3	0.0, 1.8	0.4, 2.7	0.0, 2.3
Min, Max	0.0, 9.1	0.0, 8.2	0.0, 9.1
Negative Binomial Model			
Adjusted for Strata			
Rate of RBC transfusion with 95% CI (units/month)	0.84 (0.60, 1.18)	1.84 (1.34, 2.53)	
Ratio of Rate for RBC Transfusion with 95% CI	0.46 (0.30, 0.70)	-	-
p-value	< 0.001	-	-
Unadjusted for Strata			
Rate of RBC transfusion with 95% CI (units/month)	1.12 (0.81, 1.56)	1.83 (1.36, 2.48)	
Ratio of Rate for RBC Transfusion with 95% CI	0.61 (0.39, 0.96)	-	-
p-value	0.031	-	-
Proportional Means Model - Supportive Analysis			
Stratified			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.55 (0.38, 0.79)	-	-
p-value	0.001	-	-
Unstratified			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.61 (0.41, 0.92)	-	-
p-value	0.017	-	-

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-rbc-db-csr.sas V.03.05 Output file: t-rbc-db-csr.pdf 29AUG2023: 9:34

Table 2.1601: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Total number of RBC transfusion unit in DB phase			
N	86	94	180
Mean (SD)	5.3 (8.62)	9.5 (9.97)	7.5 (9.56)
Median	2.0	6.5	4.0
Q1, Q3	0.0, 7.0	2.0, 14.0	0.0, 12.0
Min, Max	0.0, 47.0	0.0, 44.0	0.0, 47.0
Duration of the DB phase (months)			
N	86	94	180
Mean (SD)	4.96 (1.489)	5.42 (0.551)	5.20 (1.124)
Median	5.55	5.55	5.55
Q1, Q3	5.45, 5.59	5.49, 5.59	5.49, 5.59
Min, Max	0.30, 5.78	2.56, 5.78	0.30, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019

Table 2.1601: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Stratum 1			
Transfusion Dependence at Baseline = 'Yes' and Platelet Count < 100*10E9/L			
RBC transfusion Rate in DB phase (units/month)			
N	10	9	19
Mean (SD)	1.8 (1.60)	3.7 (3.12)	2.7 (2.55)
Median	1.5	3.5	3.2
Q1, Q3	0.4, 3.3	0.4, 5.2	0.4, 4.3
Min, Max	0.0, 4.3	0.0, 8.2	0.0, 8.2
Negative Binomial Model			
Rate of RBC transfusion with 95% CI (units/month)	1.82 (0.90, 3.68)	3.67 (1.78, 7.58)	
Ratio of Rate for RBC Transfusion with 95% CI	0.50 (0.18, 1.36)	-	-
Proportional Means Model - Supportive Analysis			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.52 (0.24, 1.13)	-	-
Total number of RBC transfusion in stratum 1 in DB phase			
N	10	9	19
Mean (SD)	9.0 (8.49)	16.7 (14.14)	12.6 (11.85)
Median	6.5	18.0	9.0
Q1, Q3	2.0, 18.0	2.0, 27.0	2.0, 24.0
Min, Max	0.0, 24.0	0.0, 38.0	0.0, 38.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019

Table 2.1601: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Duration of the DB phase (months) in stratum 1			
N	10	9	19
Mean (SD)	5.18 (1.174)	4.88 (1.129)	5.04 (1.131)
Median	5.55	5.52	5.55
Q1, Q3	5.49, 5.59	4.63, 5.55	5.49, 5.59
Min, Max	1.84, 5.62	2.56, 5.62	1.84, 5.62

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Table 2.1601: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Stratum 2			
Transfusion Dependence at Baseline = 'Yes' and Platelet Count >= 100*10E9/L and <= 200*10E9/L			
RBC transfusion Rate in DB phase (units/month)			
N	20	18	38
Mean (SD)	1.9 (2.46)	2.3 (2.29)	2.1 (2.36)
Median	1.2	1.3	1.2
Q1, Q3	0.0, 2.7	0.7, 4.1	0.4, 3.6
Min, Max	0.0, 9.1	0.0, 6.9	0.0, 9.1
Negative Binomial Model			
Rate of RBC transfusion with 95% CI (units/month)	1.88 (1.04, 3.41)	2.26 (1.22, 4.18)	
Ratio of Rate for RBC Transfusion with 95% CI	0.83 (0.35, 1.96)	-	-
Proportional Means Model - Supportive Analysis			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.90 (0.41, 1.94)	-	-
Total number of RBC transfusion in stratum 2 in DB phase			
N	20	18	38
Mean (SD)	8.9 (13.18)	10.8 (10.59)	9.8 (11.90)
Median	3.5	7.0	4.0
Q1, Q3	0.0, 7.5	4.0, 19.0	2.0, 13.0
Min, Max	0.0, 47.0	0.0, 38.0	0.0, 47.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019

Table 2.1601: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Duration of the DB phase (months) in stratum 2			
N	20	18	38
Mean (SD)	4.75 (1.732)	5.18 (0.834)	4.95 (1.381)
Median	5.55	5.50	5.55
Q1, Q3	5.34, 5.59	5.36, 5.55	5.36, 5.59
Min, Max	0.53, 5.65	2.76, 5.68	0.53, 5.68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Table 2.1601: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Stratum 3			
Transfusion Dependence at Baseline = 'Yes' and Platelet Count > 200*10E9/L			
RBC transfusion Rate in DB phase (units/month)			
N	19	16	35
Mean (SD)	1.4 (1.22)	2.8 (2.10)	2.0 (1.81)
Median	0.9	2.6	1.8
Q1, Q3	0.4, 2.5	1.2, 4.2	0.4, 2.9
Min, Max	0.0, 3.6	0.0, 7.8	0.0, 7.8
Negative Binomial Model			
Rate of RBC transfusion with 95% CI (units/month)	1.40 (0.91, 2.15)	2.82 (1.81, 4.38)	
Ratio of Rate for RBC Transfusion with 95% CI	0.50 (0.27, 0.92)	-	-
Proportional Means Model - Supportive Analysis			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.50 (0.29, 0.85)	-	-
Total number of RBC transfusion in stratum 3 in DB phase			
N	19	16	35
Mean (SD)	6.9 (6.84)	15.7 (11.84)	10.9 (10.31)
Median	4.0	14.0	8.0
Q1, Q3	2.0, 14.0	6.5, 24.0	2.0, 16.0
Min, Max	0.0, 20.0	0.0, 44.0	0.0, 44.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-rbc-db-csr.sas V.03.05 Output file: t-rbc-db-csr.pdf 29AUG2023: 9:34

Table 2.1601: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Duration of the DB phase (months) in stratum 3			
N	19	16	35
Mean (SD)	4.94 (1.553)	5.55 (0.101)	5.22 (1.174)
Median	5.55	5.55	5.55
Q1, Q3	5.52, 5.59	5.50, 5.59	5.52, 5.59
Min, Max	0.30, 5.65	5.32, 5.78	0.30, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Table 2.1601: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Stratum 4			
Transfusion Dependence at Baseline = 'No' and Platelet Count < 100*10E9/L			
RBC transfusion Rate in DB phase (units/month)			
N	3	4	7
Mean (SD)	0.9 (1.53)	1.1 (0.96)	1.0 (1.12)
Median	0.0	1.1	0.6
Q1, Q3	0.0, 2.7	0.3, 1.9	0.0, 2.1
Min, Max	0.0, 2.7	0.0, 2.1	0.0, 2.7
Negative Binomial Model			
Rate of RBC transfusion with 95% CI (units/month)	0.89 (0.14, 5.72)	1.07 (0.22, 5.33)	
Ratio of Rate for RBC Transfusion with 95% CI	0.83 (0.07, 9.69)	-	-
Proportional Means Model - Supportive Analysis			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.77 (0.13, 4.56)	-	-
Total number of RBC transfusion in stratum 4 in DB phase			
N	3	4	7
Mean (SD)	5.0 (8.66)	6.0 (5.48)	5.6 (6.35)
Median	0.0	6.0	3.0
Q1, Q3	0.0, 15.0	1.5, 10.5	0.0, 12.0
Min, Max	0.0, 15.0	0.0, 12.0	0.0, 15.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019

Table 2.1601: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Duration of the DB phase (months) in stratum 4			
N	3	4	7
Mean (SD)	5.60 (0.050)	5.38 (0.404)	5.47 (0.309)
Median	5.59	5.50	5.55
Q1, Q3	5.55, 5.65	5.13, 5.63	5.45, 5.65
Min, Max	5.55, 5.65	4.80, 5.72	4.80, 5.72

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Table 2.1601: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Stratum 5			
Transfusion Dependence at Baseline = 'No' and Platelet Count >= 100*10E9/L and <= 200*10E9/L			
RBC transfusion Rate in DB phase (units/month)			
N	16	16	32
Mean (SD)	0.5 (1.69)	1.1 (0.96)	0.8 (1.38)
Median	0.0	0.9	0.1
Q1, Q3	0.0, 0.0	0.3, 1.8	0.0, 1.1
Min, Max	0.0, 6.8	0.0, 3.2	0.0, 6.8
Negative Binomial Model			
Rate of RBC transfusion with 95% CI (units/month)	0.14 (0.05, 0.38)	1.08 (0.55, 2.11)	
Ratio of Rate for RBC Transfusion with 95% CI	0.13 (0.04, 0.43)	-	-
Proportional Means Model - Supportive Analysis			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.10 (0.03, 0.42)	-	-
Total number of RBC transfusion in stratum 5 in DB phase			
N	16	16	32
Mean (SD)	0.6 (1.55)	6.0 (5.34)	3.3 (4.75)
Median	0.0	5.0	0.5
Q1, Q3	0.0, 0.0	1.5, 10.0	0.0, 6.0
Min, Max	0.0, 6.0	0.0, 18.0	0.0, 18.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Table 2.1601: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Duration of the DB phase (months) in stratum 5			
N	16	16	32
Mean (SD)	5.02 (1.434)	5.57 (0.103)	5.30 (1.038)
Median	5.52	5.55	5.55
Q1, Q3	5.45, 5.55	5.52, 5.60	5.47, 5.59
Min, Max	0.30, 5.62	5.39, 5.78	0.30, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Table 2.1601: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Stratum 6			
Transfusion Dependence at Baseline = 'No' and Platelet Count > 200*10E9/L			
RBC transfusion Rate in DB phase (units/month)			
N	18	31	49
Mean (SD)	0.4 (0.89)	1.0 (1.20)	0.8 (1.13)
Median	0.0	0.7	0.2
Q1, Q3	0.0, 0.2	0.0, 1.5	0.0, 1.2
Min, Max	0.0, 3.0	0.0, 4.3	0.0, 4.3
Negative Binomial Model			
Rate of RBC transfusion with 95% CI (units/month)	0.41 (0.17, 0.96)	1.04 (0.56, 1.90)	
Ratio of Rate for RBC Transfusion with 95% CI	0.39 (0.14, 1.12)	-	-
Proportional Means Model - Supportive Analysis			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.40 (0.14, 1.18)	-	-
Total number of RBC transfusion in stratum 6 in DB phase			
N	18	31	49
Mean (SD)	2.0 (4.49)	5.8 (6.70)	4.4 (6.21)
Median	0.0	4.0	1.0
Q1, Q3	0.0, 1.0	0.0, 8.0	0.0, 7.0
Min, Max	0.0, 14.0	0.0, 24.0	0.0, 24.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-rbc-db-csr.sas V.03.05 Output file: t-rbc-db-csr.pdf 29AUG2023: 9:34

Table 2.1601: Analysis of Rate of RBC Transfusion
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	Total (N=180)
Duration of the DB phase (months) in stratum 6			
N	18	31	49
Mean (SD)	4.92 (1.573)	5.58 (0.101)	5.34 (0.992)
Median	5.54	5.55	5.55
Q1, Q3	5.29, 5.59	5.52, 5.62	5.52, 5.62
Min, Max	0.62, 5.78	5.36, 5.78	0.62, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

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Table 2.4502: Analysis of Time to First Unit of Any Type Transfused by Age
Double-blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Subjects with Event					
First Unit of Any Type Transfused, n(%)	13 (54.2%)	24 (66.7%)	36 (58.1%)	50 (86.2%)	
Censor					
Subjects Censored, n(%)	11 (45.8%)	12 (33.3%)	26 (41.9%)	8 (13.8%)	
Kaplan-Meier Estimate of Time to First Unit of Any Type Transfused (Weeks)					
25-percentile (95% CI)	2.64 (0.29, 5.86)	4.14 (1.86, 4.71)	2.00 (0.71, 4.29)	1.86 (0.86, 3.00)	
Median (95% CI)	22.71 (3.14, NE)	6.36 (4.71, 14.29)	9.86 (4.29, NE)	4.14 (3.29, 5.14)	
75-percentile (95% CI)	NE (24.14, NE)	NE (10.29, NE)	NE (NE, NE)	8.43 (5.14, 16.43)	
Min, Max	0.29, 24.43	0.57, 24.57	0.29, 24.71	0.29, 25.14	
Stratified Log-Rank Test p-value	0.92		< 0.001		
Adjusted Hazard Ratio (95% CI)	0.92 (0.44, 1.92)		0.39 (0.24, 0.62)		
Unstratified Log-Rank Test p-value	0.52		0.004		
Unadjusted Hazard Ratio (95% CI)	0.80 (0.41, 1.57)		0.53 (0.35, 0.82)		
P-value for interaction test					0.058

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-tte-any-tran-sub.sas V.03.05 Output file: t-tte-any-tran-age.pdf 24AUG2023:11:03

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Table 2.4504: Analysis of Time to First Unit of Any Type Transfused by Region
Double-blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Subjects with Event					
First Unit of Any Type Transfused, n(%)	36 (67.9%)	42 (82.4%)	13 (39.4%)	32 (74.4%)	
Censor					
Subjects Censored, n(%)	17 (32.1%)	9 (17.6%)	20 (60.6%)	11 (25.6%)	
Kaplan-Meier Estimate of Time to First Unit of Any Type Transfused (Weeks)					
25-percentile (95% CI)	1.29 (0.43, 2.43)	1.57 (0.86, 2.57)	4.29 (0.29, 11.43)	4.14 (2.00, 4.71)	
Median (95% CI)	6.14 (2.00, 17.29)	4.00 (2.29, 5.14)	NE (8.14, NE)	6.71 (4.43, 9.86)	
75-percentile (95% CI)	NE (17.29, NE)	9.29 (4.86, NE)	NE (NE, NE)	NE (8.43, NE)	
Min, Max	0.29, 24.57	0.29, 24.57	0.29, 24.71	0.29, 25.14	
Stratified Log-Rank Test p-value	0.009		0.023		
Adjusted Hazard Ratio (95% CI)	0.49 (0.30, 0.79)		0.46 (0.24, 0.89)		
Unstratified Log-Rank Test p-value	0.14		0.015		
Unadjusted Hazard Ratio (95% CI)	0.72 (0.46, 1.12)		0.46 (0.24, 0.88)		
P-value for interaction test					0.98

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019

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Table 2.4507: Analysis of Time to First Unit of Any Type Transfused by Baseline Hemoglobin Level
Double-blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Subjects with Event					
First Unit of Any Type Transfused, n(%)	21 (75.0%)	19 (90.5%)	28 (48.3%)	55 (75.3%)	
Censor					
Subjects Censored, n(%)	7 (25.0%)	2 (9.5%)	30 (51.7%)	18 (24.7%)	
Kaplan-Meier Estimate of Time to First Unit of Any Type Transfused (Weeks)					
25-percentile (95% CI)	0.93 (0.29, 2.14)	1.29 (0.29, 2.14)	4.29 (1.00, 10.00)	3.29 (1.86, 4.14)	
Median (95% CI)	3.14 (1.43, 5.86)	3.29 (1.29, 4.71)	24.14 (10.00, NE)	6.14 (4.29, 7.71)	
75-percentile (95% CI)	8.14 (4.29, NE)	6.00 (3.86, NE)	NE (NE, NE)	16.43 (8.43, NE)	
Min, Max	0.29, 24.57	0.29, 24.14	0.29, 24.71	0.29, 25.14	
Stratified Log-Rank Test p-value	0.50		< 0.001		
Adjusted Hazard Ratio (95% CI)	0.84 (0.45, 1.57)		0.46 (0.29, 0.74)		
Unstratified Log-Rank Test p-value	0.50		0.003		
Unadjusted Hazard Ratio (95% CI)	0.80 (0.43, 1.49)		0.51 (0.32, 0.80)		
P-value for interaction test					0.21

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-tte-any-tran-sub.sas V.03.05 Output file: t-tte-any-tran-hgb.pdf 24AUG2023:11:04

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Table 2.4506: Analysis of Time to First Unit of Any Type Transfused by Baseline IPSS Two-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Subjects with Event					
First Unit of Any Type Transfused, n(%)	13 (46.4%)	17 (70.8%)	36 (62.1%)	57 (81.4%)	
Censor					
Subjects Censored, n(%)	15 (53.6%)	7 (29.2%)	22 (37.9%)	13 (18.6%)	
Kaplan-Meier Estimate of Time to First Unit of Any Type Transfused (Weeks)					
25-percentile (95% CI)	2.64 (0.29, 10.14)	3.57 (1.29, 4.57)	2.00 (0.71, 4.29)	2.14 (0.86, 3.29)	
Median (95% CI)	24.14 (4.29, NE)	6.14 (3.86, 10.29)	9.86 (4.29, 24.14)	4.71 (3.57, 6.14)	
75-percentile (95% CI)	NE (NE, NE)	NE (6.43, NE)	NE (24.14, NE)	14.14 (6.71, NE)	
Min, Max	0.29, 24.43	1.29, 24.57	0.29, 24.71	0.29, 25.14	
Stratified Log-Rank Test p-value	0.074		0.023		
Adjusted Hazard Ratio (95% CI)	0.45 (0.20, 1.00)		0.62 (0.40, 0.94)		
Unstratified Log-Rank Test p-value	0.21		0.045		
Unadjusted Hazard Ratio (95% CI)	0.63 (0.31, 1.31)		0.65 (0.43, 0.99)		
P-value for interaction test					0.55

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-tte-any-tran-sub.sas V.03.05 Output file: t-tte-any-tran-ipss2.pdf 24AUG2023:11:04

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Table 2.4505: Analysis of Time to First Unit of Any Type Transfused by Baseline IPSS Three-Level Risk

Double-blind Phase

ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Subjects with Event				
First Unit of Any Type Transfused, n(%)	0	3 (75.0%)	13 (50.0%)	14 (70.0%)
Censor				
Subjects Censored, n(%)	2 (100.0%)	1 (25.0%)	13 (50.0%)	6 (30.0%)
Kaplan-Meier Estimate of Time to First Unit of Any Type Transfused (Weeks)				
25-percentile (95% CI)	NE (NE, NE)	4.21 (3.86, 4.71)	2.14 (0.29, 8.14)	2.79 (1.29, 6.00)
Median (95% CI)	NE (NE, NE)	4.64 (3.86, NE)	24.14 (3.14, NE)	6.36 (2.29, NE)
75-percentile (95% CI)	NE (NE, NE)	NE (3.86, NE)	NE (NE, NE)	NE (6.43, NE)
Min, Max	23.71, 24.14	3.86, 24.43	0.29, 24.43	1.29, 24.57
Stratified Log-Rank Test p-value	NA		NA	
Adjusted Hazard Ratio (95% CI)	NA		NA	
Unstratified Log-Rank Test p-value	NA		NA	
Unadjusted Hazard Ratio (95% CI)	NA		NA	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.4505: Analysis of Time to First Unit of Any Type Transfused by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=58)	High Risk RUX (N=70)	p-value
Subjects with Event			
First Unit of Any Type Transfused, n(%)	36 (62.1%)	57 (81.4%)	
Censor			
Subjects Censored, n(%)	22 (37.9%)	13 (18.6%)	
Kaplan-Meier Estimate of Time to First Unit of Any Type Transfused (Weeks)			
25-percentile (95% CI)	2.00 (0.71, 4.29)	2.14 (0.86, 3.29)	
Median (95% CI)	9.86 (4.29, 24.14)	4.71 (3.57, 6.14)	
75-percentile (95% CI)	NE (24.14, NE)	14.14 (6.71, NE)	
Min, Max	0.29, 24.71	0.29, 25.14	
Stratified Log-Rank Test p-value	NA		
Adjusted Hazard Ratio (95% CI)	NA		
Unstratified Log-Rank Test p-value	NA		
Unadjusted Hazard Ratio (95% CI)	NA		
P-value for interaction test			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-tte-any-tran-sub.sas V.03.05 Output file: t-tte-any-tran-ipss3.pdf 24AUG2023:11:04

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Table 2.4508: Analysis of Time to First Unit of Any Type Transfused by Baseline MF Disease Status

Double-blind Phase

ITT-Anemic Analysis Set

	Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=16)	RUX (N=28)	MMB (N=11)	RUX (N=12)
Subjects with Event				
First Unit of Any Type Transfused, n(%)	12 (75.0%)	21 (75.0%)	5 (45.5%)	11 (91.7%)
Censor				
Subjects Censored, n(%)	4 (25.0%)	7 (25.0%)	6 (54.5%)	1 (8.3%)
Kaplan-Meier Estimate of Time to First Unit of Any Type Transfused (Weeks)				
25-percentile (95% CI)	0.86 (0.29, 5.29)	2.00 (0.29, 4.14)	0.71 (0.29, NE)	0.64 (0.29, 3.57)
Median (95% CI)	6.50 (0.71, 24.14)	4.79 (2.14, 9.29)	NE (0.29, NE)	3.79 (0.43, 6.71)
75-percentile (95% CI)	24.14 (5.29, NE)	NE (6.00, NE)	NE (2.43, NE)	6.43 (3.57, NE)
Min, Max	0.29, 24.71	0.29, 24.71	0.29, 24.57	0.29, 24.57
Stratified Log-Rank Test p-value	0.80		0.19	
Adjusted Hazard Ratio (95% CI)	1.05 (0.46, 2.41)		0.39 (0.12, 1.30)	
Unstratified Log-Rank Test p-value	0.94		0.11	
Unadjusted Hazard Ratio (95% CI)	0.97 (0.48, 1.98)		0.44 (0.15, 1.28)	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.4508: Analysis of Time to First Unit of Any Type Transfused by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	Primary Myelofibrosis MMB (N=59)	Primary Myelofibrosis RUX (N=54)	p-value
Subjects with Event			
First Unit of Any Type Transfused, n(%)	32 (54.2%)	42 (77.8%)	
Censor			
Subjects Censored, n(%)	27 (45.8%)	12 (22.2%)	
Kaplan-Meier Estimate of Time to First Unit of Any Type Transfused (Weeks)			
25-percentile (95% CI)	2.14 (1.14, 4.29)	3.29 (1.86, 4.14)	
Median (95% CI)	11.43 (4.29, NE)	5.14 (4.14, 6.71)	
75-percentile (95% CI)	NE (NE, NE)	14.14 (6.71, NE)	
Min, Max	0.29, 24.43	0.29, 25.14	
Stratified Log-Rank Test p-value	0.042		
Adjusted Hazard Ratio (95% CI)	0.54 (0.34, 0.88)		
Unstratified Log-Rank Test p-value	0.034		
Unadjusted Hazard Ratio (95% CI)	0.61 (0.38, 0.97)		
P-value for interaction test			0.12

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019

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Table 2.4503: Analysis of Time to First Unit of Any Type Transfused by Gender
Double-blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Subjects with Event					
First Unit of Any Type Transfused, n(%)	35 (70.0%)	47 (83.9%)	14 (38.9%)	27 (71.1%)	
Censor					
Subjects Censored, n(%)	15 (30.0%)	9 (16.1%)	22 (61.1%)	11 (28.9%)	
Kaplan-Meier Estimate of Time to First Unit of Any Type Transfused (Weeks)					
25-percentile (95% CI)	1.14 (0.43, 2.14)	2.14 (1.14, 3.29)	4.29 (1.29, 24.14)	3.57 (0.86, 4.29)	
Median (95% CI)	6.00 (2.00, 12.00)	4.64 (3.29, 6.00)	NE (9.86, NE)	6.29 (4.14, 10.29)	
75-percentile (95% CI)	NE (11.43, NE)	9.14 (6.14, NE)	NE (NE, NE)	NE (8.43, NE)	
Min, Max	0.29, 24.71	0.29, 25.14	0.29, 24.29	0.29, 24.71	
Stratified Log-Rank Test p-value	0.025		0.073		
Adjusted Hazard Ratio (95% CI)	0.57 (0.36, 0.90)		0.53 (0.27, 1.02)		
Unstratified Log-Rank Test p-value	0.19		0.021		
Unadjusted Hazard Ratio (95% CI)	0.75 (0.48, 1.16)		0.48 (0.25, 0.91)		
P-value for interaction test					0.84

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019

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Table 2.4510: Analysis of Time to First Unit of Any Type Transfused by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Subjects with Event					
First Unit of Any Type Transfused, n(%)	23 (48.9%)	34 (79.1%)	26 (66.7%)	40 (78.4%)	
Censor					
Subjects Censored, n(%)	24 (51.1%)	9 (20.9%)	13 (33.3%)	11 (21.6%)	
Kaplan-Meier Estimate of Time to First Unit of Any Type Transfused (Weeks)					
25-percentile (95% CI)	2.00 (0.71, 6.14)	2.57 (1.14, 3.57)	1.14 (0.43, 4.29)	2.29 (0.86, 4.43)	
Median (95% CI)	24.14 (5.86, NE)	4.14 (3.29, 6.14)	7.71 (2.43, 12.29)	5.14 (4.14, 9.86)	
75-percentile (95% CI)	NE (NE, NE)	8.43 (6.14, NE)	NE (11.43, NE)	15.86 (8.14, NE)	
Min, Max	0.29, 24.71	0.29, 25.14	0.29, 24.57	0.29, 24.57	
Stratified Log-Rank Test p-value	0.001		0.27		
Adjusted Hazard Ratio (95% CI)	0.33 (0.18, 0.61)		0.78 (0.47, 1.31)		
Unstratified Log-Rank Test p-value	0.009		0.54		
Unadjusted Hazard Ratio (95% CI)	0.50 (0.29, 0.85)		0.86 (0.52, 1.41)		
P-value for interaction test					0.070

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019

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Table 2.4509: Analysis of Time to First Unit of Any Type Transfused by Baseline TSS
Double-blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Subjects with Event					
First Unit of Any Type Transfused, n(%)	25 (56.8%)	43 (78.2%)	23 (56.1%)	30 (78.9%)	
Censor					
Subjects Censored, n(%)	19 (43.2%)	12 (21.8%)	18 (43.9%)	8 (21.1%)	
Kaplan-Meier Estimate of Time to First Unit of Any Type Transfused (Weeks)					
25-percentile (95% CI)	2.14 (0.43, 6.14)	2.71 (1.57, 4.00)	1.29 (0.43, 4.29)	2.14 (0.71, 4.00)	
Median (95% CI)	11.43 (5.29, NE)	4.71 (4.00, 6.43)	7.71 (3.14, NE)	4.86 (3.29, 9.29)	
75-percentile (95% CI)	NE (24.14, NE)	14.29 (6.43, NE)	NE (24.14, NE)	14.29 (6.71, NE)	
Min, Max	0.29, 24.43	0.29, 25.14	0.29, 24.71	0.43, 24.71	
Stratified Log-Rank Test p-value	0.015		0.10		
Adjusted Hazard Ratio (95% CI)	0.54 (0.33, 0.89)		0.58 (0.33, 1.03)		
Unstratified Log-Rank Test p-value	0.049		0.15		
Unadjusted Hazard Ratio (95% CI)	0.61 (0.37, 1.00)		0.68 (0.39, 1.17)		
P-value for interaction test					0.73

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.4501: Analysis of Time to First Unit of Any Type Transfused
Double-blind Phase
ITT-Anemic Analysis Set

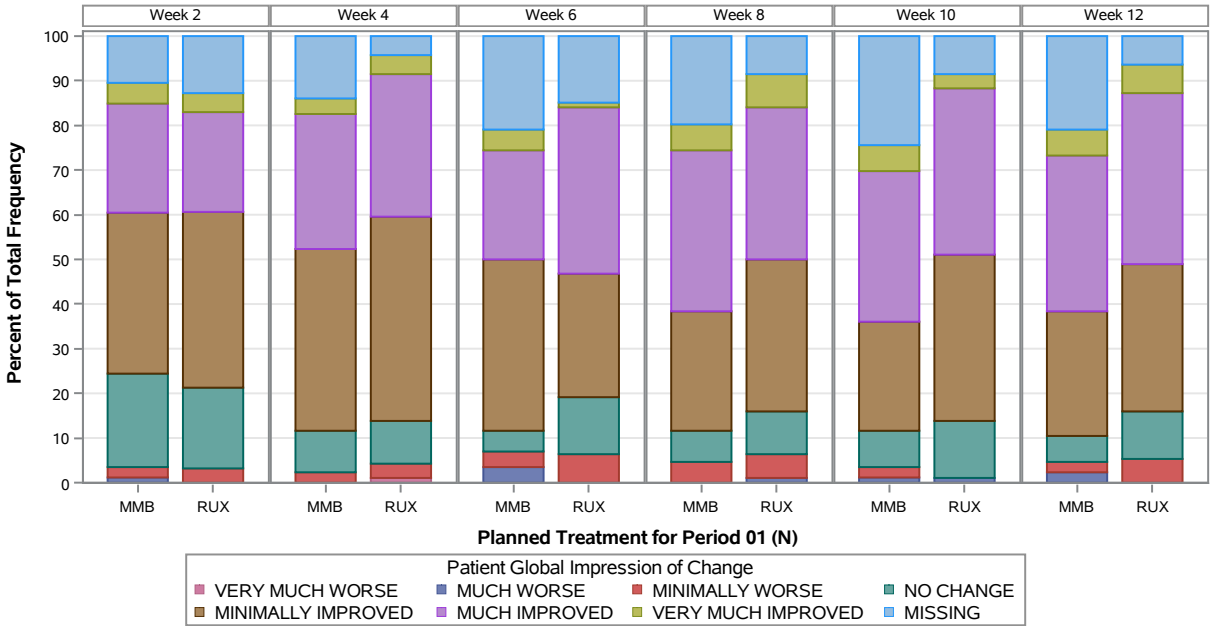
	MMB (N=86)	RUX (N=94)
Subjects with Event		
First Unit of Any Type Transfused, n(%)	49 (57.0%)	74 (78.7%)
Censor		
Subjects Censored, n(%)	37 (43.0%)	20 (21.3%)
Kaplan-Meier Estimate of Time to First Unit of Any Type Transfused (Weeks)		
25-percentile (95% CI)	2.00 (0.71, 4.29)	2.57 (1.29, 3.57)
Median (95% CI)	10.14 (5.14, NE)	4.71 (4.14, 6.29)
75-percentile (95% CI)	NE (NE, NE)	14.29 (7.71, NE)
Min, Max	0.29, 24.71	0.29, 25.14
Stratified Log-Rank Test p-value	0.003	
Adjusted Hazard Ratio (95% CI)	0.57 (0.39, 0.82)	
Unstratified Log-Rank Test p-value	0.013	
Unadjusted Hazard Ratio (95% CI)	0.64 (0.44, 0.91)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-tte-any-tran.sas V.03.05 Output file: t-tte-any-tran.pdf 24AUG2023:11:03

1.7 PGIC

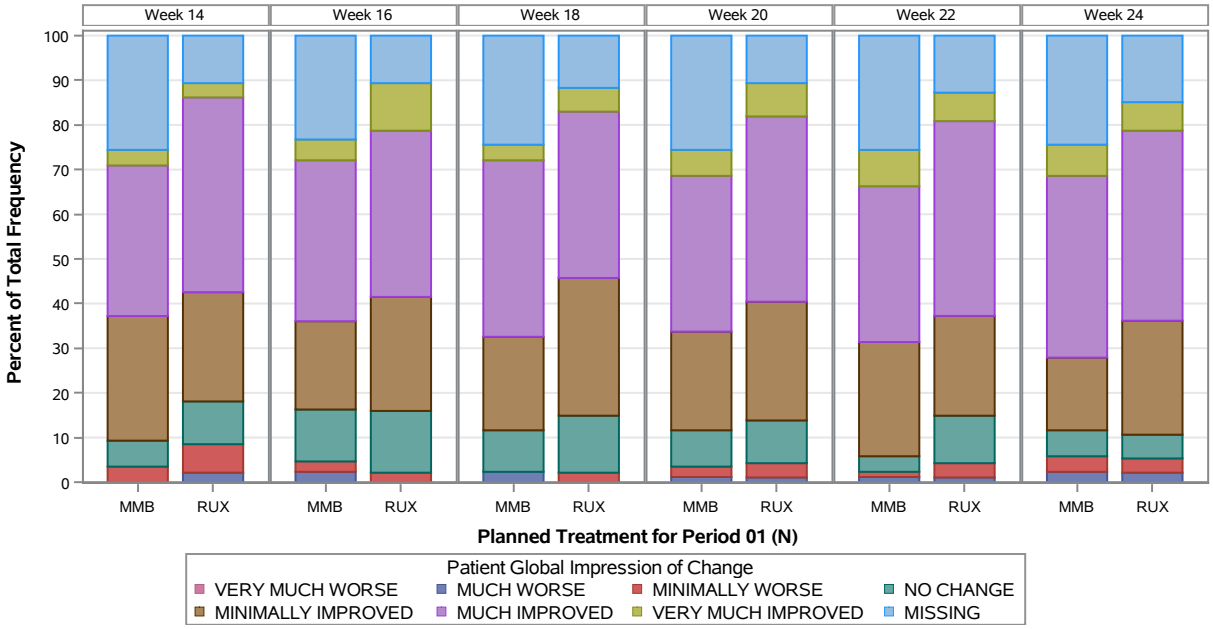
Figure 2.3801: Stacked Bar Chart of Patient Global Impression of Change Over Time
Double-Blind Phase
ITT-Anemic Analysis Set



ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 01JUL2019
Source: g-pgic-bar-gba.sas V.03.05 Output file: g-pgic-bar.pdf
30AUG2023:12:28

Figure 2.3801: Stacked Bar Chart of Patient Global Impression of Change Over Time
Double-Blind Phase
ITT-Anemic Analysis Set



ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 01JUL2019
Source: g-pgic-bar-gba.sas V.03.05 Output file: g-pgic-bar.pdf
30AUG2023:12:28

Table 2.6601: Analysis of Patient Global Impression of Change (PGIC)
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-label Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 64)	Switch (RUX->MMB) (N = 84)	Total (N = 148)	MMB in Double-blind (N = 86)	Total (N = 170)
Best PGIC Assessment at Any Timepoint of Overall Exposed to MMB, n (%)					
Improvement, n(%)				76 (88.4%)	144 (84.7%)
Very much improved				27 (31.4%)	41 (24.1%)
Much improved				36 (41.9%)	75 (44.1%)
Minimally improved				13 (15.1%)	28 (16.5%)
95% Exact CI				0.7965, 0.9428	0.7840, 0.8976
Worsening, n(%)				3 (3.5%)	9 (5.3%)
Minimally worse				2 (2.3%)	8 (4.7%)
Much worse				1 (1.2%)	1 (0.6%)
Very much worse				0	0
95% Exact CI				0.0073, 0.0986	0.0245, 0.0981
Missing Assessment				4 (4.7%)	13 (7.6%)
No change				3 (3.5%)	4 (2.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-pgic-ext.sas V.03.05 Output file: t-chg-pgic-ext.pdf 29AUG2023: 9:40

Table 2.6601: Analysis of Patient Global Impression of Change (PGIC)
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-label Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 64)	Switch (RUX->MMB) (N = 84)	Total (N = 148)	MMB in Double-blind (N = 86)	Total (N = 170)
Best PGIC Assessment at Any Timepoint in Open-label Phase, n (%)					
Subjects Ongoing and not Reach the 1st Assessment Timepoint in Open-label Phase	0	0	0		
Subjects discontinued or Reached the 1st Assessment Timepoint in Open-label Phase	64	84	148		
Improvement, n(%)	54 (84.4%)	68 (81.0%)	122 (82.4%)		
Very much improved	17 (26.6%)	14 (16.7%)	31 (20.9%)		
Much improved	21 (32.8%)	39 (46.4%)	60 (40.5%)		
Minimally improved	16 (25.0%)	15 (17.9%)	31 (20.9%)		
95% Exact CI	0.7314, 0.9224	0.7092, 0.8870	0.7533, 0.8819		
Worsening, n(%)	2 (3.1%)	6 (7.1%)	8 (5.4%)		
Minimally worse	1 (1.6%)	6 (7.1%)	7 (4.7%)		
Much worse	0	0	0		
Very much worse	1 (1.6%)	0	1 (0.7%)		
95% Exact CI	0.0038, 0.1084	0.0267, 0.1490	0.0236, 0.1037		
Missing Assessment	4 (6.3%)	9 (10.7%)	13 (8.8%)		
No change	4 (6.3%)	1 (1.2%)	5 (3.4%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.

Table 2.6601: Analysis of Patient Global Impression of Change (PGIC)
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-label Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 64)	Switch (RUX->MMB) (N = 84)	Total (N = 148)	MMB in Double-blind (N = 86)	Total (N = 170)
Week 24 in Open-label Phase, n(%)					
Subjects Ongoing and not Reach Week 24 in Open-label Phase	0	0	0		
Subjects Evaluable for Analysis of PGIC at Week 24 in Open-label Phase	64	84	148		
Improvement, n(%)	39 (60.9%)	52 (61.9%)	91 (61.5%)		
Very much improved	5 (7.8%)	6 (7.1%)	11 (7.4%)		
Much improved	16 (25.0%)	28 (33.3%)	44 (29.7%)		
Minimally improved	18 (28.1%)	18 (21.4%)	36 (24.3%)		
95% Exact CI	0.4793, 0.7290	0.5066, 0.7229	0.5314, 0.6936		
Worsening, n(%)	4 (6.3%)	6 (7.1%)	10 (6.8%)		
Minimally worse	3 (4.7%)	4 (4.8%)	7 (4.7%)		
Much worse	1 (1.6%)	2 (2.4%)	3 (2.0%)		
Very much worse	0	0	0		
95% Exact CI	0.0173, 0.1524	0.0267, 0.1490	0.0329, 0.1207		
Missing Assessment	16 (25.0%)	20 (23.8%)	36 (24.3%)		
No change	5 (7.8%)	6 (7.1%)	11 (7.4%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.

Table 2.6601: Analysis of Patient Global Impression of Change (PGIC)
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-label Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 64)	Switch (RUX->MMB) (N = 84)	Total (N = 148)	MMB in Double-blind (N = 86)	Total (N = 170)
Week 12 in Open-label Phase, n(%)					
Subjects Ongoing and not Reach Week 12 in Open-label Phase	0	0	0		
Subjects Evaluable for Analysis of PGIC at Week 12 in Open-label Phase	64	84	148		
Improvement, n(%)	41 (64.1%)	55 (65.5%)	96 (64.9%)		
Very much improved	7 (10.9%)	5 (6.0%)	12 (8.1%)		
Much improved	21 (32.8%)	27 (32.1%)	48 (32.4%)		
Minimally improved	13 (20.3%)	23 (27.4%)	36 (24.3%)		
95% Exact CI	0.5110, 0.7568	0.5431, 0.7552	0.5660, 0.7252		
Worsening, n(%)	3 (4.7%)	5 (6.0%)	8 (5.4%)		
Minimally worse	1 (1.6%)	4 (4.8%)	5 (3.4%)		
Much worse	0	1 (1.2%)	1 (0.7%)		
Very much worse	2 (3.1%)	0	2 (1.4%)		
95% Exact CI	0.0098, 0.1309	0.0196, 0.1335	0.0236, 0.1037		
Missing Assessment	13 (20.3%)	18 (21.4%)	31 (20.9%)		
No change	7 (10.9%)	6 (7.1%)	13 (8.8%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.

Data Extracted: CRF data: 01JUL2019

Table 2.6601: Analysis of Patient Global Impression of Change (PGIC)
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-label Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 64)	Switch (RUX->MMB) (N = 84)	Total (N = 148)	MMB in Double-blind (N = 86)	Total (N = 170)
Week 36 in Open-label Phase, n(%)					
Subjects Ongoing and not Reach Week 36 in Open-label Phase	0	0	0		
Subjects Evaluable for Analysis of PGIC at Week 36 in Open-label Phase	64	84	148		
Improvement, n(%)	30 (46.9%)	40 (47.6%)	70 (47.3%)		
Very much improved	11 (17.2%)	4 (4.8%)	15 (10.1%)		
Much improved	9 (14.1%)	26 (31.0%)	35 (23.6%)		
Minimally improved	10 (15.6%)	10 (11.9%)	20 (13.5%)		
95% Exact CI	0.3428, 0.5977	0.3660, 0.5881	0.3904, 0.5566		
Worsening, n(%)	1 (1.6%)	4 (4.8%)	5 (3.4%)		
Minimally worse	1 (1.6%)	3 (3.6%)	4 (2.7%)		
Much worse	0	1 (1.2%)	1 (0.7%)		
Very much worse	0	0	0		
95% Exact CI	0.0004, 0.0840	0.0131, 0.1175	0.0111, 0.0771		
Missing Assessment	24 (37.5%)	34 (40.5%)	58 (39.2%)		
No change	9 (14.1%)	6 (7.1%)	15 (10.1%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-pgic-ext.sas V.03.05 Output file: t-chg-pgic-ext.pdf 29AUG2023: 9:40

Table 2.6601: Analysis of Patient Global Impression of Change (PGIC)
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-label Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 64)	Switch (RUX->MMB) (N = 84)	Total (N = 148)	MMB in Double-blind (N = 86)	Total (N = 170)
Week 48 in Open-label Phase, n(%)					
Subjects Ongoing and not Reach Week 48 in Open-label Phase	0	0	0		
Subjects Evaluable for Analysis of PGIC at Week 48 in Open-label Phase	64	84	148		
Improvement, n(%)	35 (54.7%)	35 (41.7%)	70 (47.3%)		
Very much improved	5 (7.8%)	3 (3.6%)	8 (5.4%)		
Much improved	16 (25.0%)	20 (23.8%)	36 (24.3%)		
Minimally improved	14 (21.9%)	12 (14.3%)	26 (17.6%)		
95% Exact CI	0.4175, 0.6718	0.3100, 0.5294	0.3904, 0.5566		
Worsening, n(%)	3 (4.7%)	5 (6.0%)	8 (5.4%)		
Minimally worse	3 (4.7%)	3 (3.6%)	6 (4.1%)		
Much worse	0	2 (2.4%)	2 (1.4%)		
Very much worse	0	0	0		
95% Exact CI	0.0098, 0.1309	0.0196, 0.1335	0.0236, 0.1037		
Missing Assessment	24 (37.5%)	39 (46.4%)	63 (42.6%)		
No change	2 (3.1%)	5 (6.0%)	7 (4.7%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-pgic-ext.sas V.03.05 Output file: t-chg-pgic-ext.pdf 29AUG2023: 9:40

Table 2.6601: Analysis of Patient Global Impression of Change (PGIC)
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-label Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 64)	Switch (RUX->MMB) (N = 84)	Total (N = 148)	MMB in Double-blind (N = 86)	Total (N = 170)
Week 60 in Open-label Phase, n(%)					
Subjects Ongoing and not Reach Week 60 in Open-label Phase	0	0	0		
Subjects Evaluable for Analysis of PGIC at Week 60 in Open-label Phase	64	84	148		
Improvement, n(%)	26 (40.6%)	32 (38.1%)	58 (39.2%)		
Very much improved	6 (9.4%)	2 (2.4%)	8 (5.4%)		
Much improved	9 (14.1%)	21 (25.0%)	30 (20.3%)		
Minimally improved	11 (17.2%)	9 (10.7%)	20 (13.5%)		
95% Exact CI	0.2851, 0.5363	0.2771, 0.4934	0.3128, 0.4754		
Worsening, n(%)	4 (6.3%)	3 (3.6%)	7 (4.7%)		
Minimally worse	4 (6.3%)	3 (3.6%)	7 (4.7%)		
Much worse	0	0	0		
Very much worse	0	0	0		
95% Exact CI	0.0173, 0.1524	0.0074, 0.1008	0.0192, 0.0950		
Missing Assessment	30 (46.9%)	45 (53.6%)	75 (50.7%)		
No change	4 (6.3%)	4 (4.8%)	8 (5.4%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.

Table 2.6601: Analysis of Patient Global Impression of Change (PGIC)
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-label Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 64)	Switch (RUX->MMB) (N = 84)	Total (N = 148)	MMB in Double-blind (N = 86)	Total (N = 170)
Week 72 in Open-label Phase, n(%)					
Subjects Ongoing and not Reach Week 72 in Open-label Phase	0	0	0		
Subjects Evaluable for Analysis of PGIC at Week 72 in Open-label Phase	64	84	148		
Improvement, n(%)	20 (31.3%)	25 (29.8%)	45 (30.4%)		
Very much improved	5 (7.8%)	4 (4.8%)	9 (6.1%)		
Much improved	10 (15.6%)	14 (16.7%)	24 (16.2%)		
Minimally improved	5 (7.8%)	7 (8.3%)	12 (8.1%)		
95% Exact CI	0.2024, 0.4406	0.2027, 0.4073	0.2312, 0.3850		
Worsening, n(%)	2 (3.1%)	3 (3.6%)	5 (3.4%)		
Minimally worse	0	2 (2.4%)	2 (1.4%)		
Much worse	1 (1.6%)	1 (1.2%)	2 (1.4%)		
Very much worse	1 (1.6%)	0	1 (0.7%)		
95% Exact CI	0.0038, 0.1084	0.0074, 0.1008	0.0111, 0.0771		
Missing Assessment	37 (57.8%)	53 (63.1%)	90 (60.8%)		
No change	5 (7.8%)	3 (3.6%)	8 (5.4%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-pgic-ext.sas V.03.05 Output file: t-chg-pgic-ext.pdf 29AUG2023: 9:40

Table 2.6601: Analysis of Patient Global Impression of Change (PGIC)
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-label Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 64)	Switch (RUX->MMB) (N = 84)	Total (N = 148)	MMB in Double-blind (N = 86)	Total (N = 170)
Week 84 in Open-label Phase, n(%)					
Subjects Ongoing and not Reach Week 84 in Open-label Phase	0	0	0		
Subjects Evaluable for Analysis of PGIC at Week 84 in Open-label Phase	64	84	148		
Improvement, n(%)	21 (32.8%)	20 (23.8%)	41 (27.7%)		
Very much improved	5 (7.8%)	4 (4.8%)	9 (6.1%)		
Much improved	10 (15.6%)	11 (13.1%)	21 (14.2%)		
Minimally improved	6 (9.4%)	5 (6.0%)	11 (7.4%)		
95% Exact CI	0.2159, 0.4569	0.1519, 0.3435	0.2067, 0.3565		
Worsening, n(%)	3 (4.7%)	1 (1.2%)	4 (2.7%)		
Minimally worse	1 (1.6%)	0	1 (0.7%)		
Much worse	2 (3.1%)	1 (1.2%)	3 (2.0%)		
Very much worse	0	0	0		
95% Exact CI	0.0098, 0.1309	0.0003, 0.0646	0.0074, 0.0678		
Missing Assessment	37 (57.8%)	57 (67.9%)	94 (63.5%)		
No change	3 (4.7%)	6 (7.1%)	9 (6.1%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-pgic-ext.sas V.03.05 Output file: t-chg-pgic-ext.pdf 29AUG2023: 9:40

Table 2.6601: Analysis of Patient Global Impression of Change (PGIC)
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-label Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 64)	Switch (RUX->MMB) (N = 84)	Total (N = 148)	MMB in Double-blind (N = 86)	Total (N = 170)
Week 96 in Open-label Phase, n(%)					
Subjects Ongoing and not Reach Week 96 in Open-label Phase	0	0	0		
Subjects Evaluable for Analysis of PGIC at Week 96 in Open-label Phase	64	84	148		
Improvement, n(%)	19 (29.7%)	21 (25.0%)	40 (27.0%)		
Very much improved	4 (6.3%)	3 (3.6%)	7 (4.7%)		
Much improved	11 (17.2%)	12 (14.3%)	23 (15.5%)		
Minimally improved	4 (6.3%)	6 (7.1%)	10 (6.8%)		
95% Exact CI	0.1891, 0.4242	0.1619, 0.3564	0.2006, 0.3494		
Worsening, n(%)	2 (3.1%)	0	2 (1.4%)		
Minimally worse	2 (3.1%)	0	2 (1.4%)		
Much worse	0	0	0		
Very much worse	0	0	0		
95% Exact CI	0.0038, 0.1084	0.0000, 0.0430	0.0016, 0.0480		
Missing Assessment	41 (64.1%)	57 (67.9%)	98 (66.2%)		
No change	2 (3.1%)	6 (7.1%)	8 (5.4%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-pgic-ext.sas V.03.05 Output file: t-chg-pgic-ext.pdf 29AUG2023: 9:40

Table 2.6601: Analysis of Patient Global Impression of Change (PGIC)
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-label Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 64)	Switch (RUX->MMB) (N = 84)	Total (N = 148)	MMB in Double-blind (N = 86)	Total (N = 170)
Week 108 in Open-label Phase, n(%)					
Subjects Ongoing and not Reach Week 108 in Open-label Phase	0	0	0		
Subjects Evaluable for Analysis of PGIC at Week 108 in Open-label Phase	64	84	148		
Improvement, n(%)	15 (23.4%)	21 (25.0%)	36 (24.3%)		
Very much improved	6 (9.4%)	1 (1.2%)	7 (4.7%)		
Much improved	5 (7.8%)	13 (15.5%)	18 (12.2%)		
Minimally improved	4 (6.3%)	7 (8.3%)	11 (7.4%)		
95% Exact CI	0.1375, 0.3569	0.1619, 0.3564	0.1765, 0.3205		
Worsening, n(%)	1 (1.6%)	2 (2.4%)	3 (2.0%)		
Minimally worse	0	2 (2.4%)	2 (1.4%)		
Much worse	1 (1.6%)	0	1 (0.7%)		
Very much worse	0	0	0		
95% Exact CI	0.0004, 0.0840	0.0029, 0.0834	0.0042, 0.0581		
Missing Assessment	45 (70.3%)	58 (69.0%)	103 (69.6%)		
No change	3 (4.7%)	3 (3.6%)	6 (4.1%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-pgic-ext.sas V.03.05 Output file: t-chg-pgic-ext.pdf 29AUG2023: 9:40

Table 2.6601: Analysis of Patient Global Impression of Change (PGIC)
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-label Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 64)	Switch (RUX->MMB) (N = 84)	Total (N = 148)	MMB in Double-blind (N = 86)	Total (N = 170)
Week 120 in Open-label Phase, n(%)					
Subjects Ongoing and not Reach Week 120 in Open-label Phase	0	0	0		
Subjects Evaluable for Analysis of PGIC at Week 120 in Open-label Phase	64	84	148		
Improvement, n(%)	15 (23.4%)	18 (21.4%)	33 (22.3%)		
Very much improved	8 (12.5%)	2 (2.4%)	10 (6.8%)		
Much improved	6 (9.4%)	10 (11.9%)	16 (10.8%)		
Minimally improved	1 (1.6%)	6 (7.1%)	7 (4.7%)		
95% Exact CI	0.1375, 0.3569	0.1322, 0.3174	0.1587, 0.2986		
Worsening, n(%)	0	1 (1.2%)	1 (0.7%)		
Minimally worse	0	0	0		
Much worse	0	1 (1.2%)	1 (0.7%)		
Very much worse	0	0	0		
95% Exact CI	0.0000, 0.0560	0.0003, 0.0646	0.0002, 0.0371		
Missing Assessment	47 (73.4%)	61 (72.6%)	108 (73.0%)		
No change	2 (3.1%)	4 (4.8%)	6 (4.1%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-pgic-ext.sas V.03.05 Output file: t-chg-pgic-ext.pdf 29AUG2023: 9:40

Table 2.6601: Analysis of Patient Global Impression of Change (PGIC)
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-label Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 64)	Switch (RUX->MMB) (N = 84)	Total (N = 148)	MMB in Double-blind (N = 86)	Total (N = 170)
Week 132 in Open-label Phase, n(%)					
Subjects Ongoing and not Reach Week 132 in Open-label Phase	0	0	0		
Subjects Evaluable for Analysis of PGIC at Week 132 in Open-label Phase	64	84	148		
Improvement, n(%)	10 (15.6%)	13 (15.5%)	23 (15.5%)		
Very much improved	3 (4.7%)	0	3 (2.0%)		
Much improved	4 (6.3%)	5 (6.0%)	9 (6.1%)		
Minimally improved	3 (4.7%)	8 (9.5%)	11 (7.4%)		
95% Exact CI	0.0776, 0.2686	0.0851, 0.2501	0.1011, 0.2240		
Worsening, n(%)	3 (4.7%)	0	3 (2.0%)		
Minimally worse	0	0	0		
Much worse	2 (3.1%)	0	2 (1.4%)		
Very much worse	1 (1.6%)	0	1 (0.7%)		
95% Exact CI	0.0098, 0.1309	0.0000, 0.0430	0.0042, 0.0581		
Missing Assessment	49 (76.6%)	70 (83.3%)	119 (80.4%)		
No change	2 (3.1%)	1 (1.2%)	3 (2.0%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.

Table 2.6601: Analysis of Patient Global Impression of Change (PGIC)
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-label Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 64)	Switch (RUX->MMB) (N = 84)	Total (N = 148)	MMB in Double-blind (N = 86)	Total (N = 170)
Week 144 in Open-label Phase, n(%)					
Subjects Ongoing and not Reach Week 144 in Open-label Phase	0	0	0		
Subjects Evaluable for Analysis of PGIC at Week 144 in Open-label Phase	64	84	148		
Improvement, n(%)	6 (9.4%)	5 (6.0%)	11 (7.4%)		
Very much improved	0	0	0		
Much improved	4 (6.3%)	4 (4.8%)	8 (5.4%)		
Minimally improved	2 (3.1%)	1 (1.2%)	3 (2.0%)		
95% Exact CI	0.0352, 0.1930	0.0196, 0.1335	0.0377, 0.1291		
Worsening, n(%)	0	1 (1.2%)	1 (0.7%)		
Minimally worse	0	1 (1.2%)	1 (0.7%)		
Much worse	0	0	0		
Very much worse	0	0	0		
95% Exact CI	0.0000, 0.0560	0.0003, 0.0646	0.0002, 0.0371		
Missing Assessment	56 (87.5%)	76 (90.5%)	132 (89.2%)		
No change	2 (3.1%)	2 (2.4%)	4 (2.7%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-pgic-ext.sas V.03.05 Output file: t-chg-pgic-ext.pdf 29AUG2023: 9:40

Table 2.6601: Analysis of Patient Global Impression of Change (PGIC)
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-label Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 64)	Switch (RUX->MMB) (N = 84)	Total (N = 148)	MMB in Double-blind (N = 86)	Total (N = 170)
Week 156 in Open-label Phase, n(%)					
Subjects Ongoing and not Reach Week 156 in Open-label Phase	0	0	0		
Subjects Evaluable for Analysis of PGIC at Week 156 in Open-label Phase	64	84	148		
Improvement, n(%)	4 (6.3%)	2 (2.4%)	6 (4.1%)		
Very much improved	2 (3.1%)	0	2 (1.4%)		
Much improved	1 (1.6%)	1 (1.2%)	2 (1.4%)		
Minimally improved	1 (1.6%)	1 (1.2%)	2 (1.4%)		
95% Exact CI	0.0173, 0.1524	0.0029, 0.0834	0.0150, 0.0861		
Worsening, n(%)	1 (1.6%)	0	1 (0.7%)		
Minimally worse	1 (1.6%)	0	1 (0.7%)		
Much worse	0	0	0		
Very much worse	0	0	0		
95% Exact CI	0.0004, 0.0840	0.0000, 0.0430	0.0002, 0.0371		
Missing Assessment	58 (90.6%)	82 (97.6%)	140 (94.6%)		
No change	1 (1.6%)	0	1 (0.7%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-pgic-ext.sas V.03.05 Output file: t-chg-pgic-ext.pdf 29AUG2023: 9:40

Table 2.6601: Analysis of Patient Global Impression of Change (PGIC)
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
ITT-Anemic Analysis Set

	Open-label Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 64)	Switch (RUX->MMB) (N = 84)	Total (N = 148)	MMB in Double-blind (N = 86)	Total (N = 170)
Week 168 in Open-label Phase, n(%)					
Subjects Ongoing and not Reach Week 168 in Open-label Phase	0	0	0		
Subjects Evaluable for Analysis of PGIC at Week 168 in Open-label Phase	64	84	148		
Improvement, n(%)	3 (4.7%)	0	3 (2.0%)		
Very much improved	2 (3.1%)	0	2 (1.4%)		
Much improved	1 (1.6%)	0	1 (0.7%)		
Minimally improved	0	0	0		
95% Exact CI	0.0098, 0.1309	0.0000, 0.0430	0.0042, 0.0581		
Worsening, n(%)	0	0	0		
Minimally worse	0	0	0		
Much worse	0	0	0		
Very much worse	0	0	0		
95% Exact CI	0.0000, 0.0560	0.0000, 0.0430	0.0000, 0.0246		
Missing Assessment	61 (95.3%)	84 (100.0%)	145 (98.0%)		
No change	0	0	0		

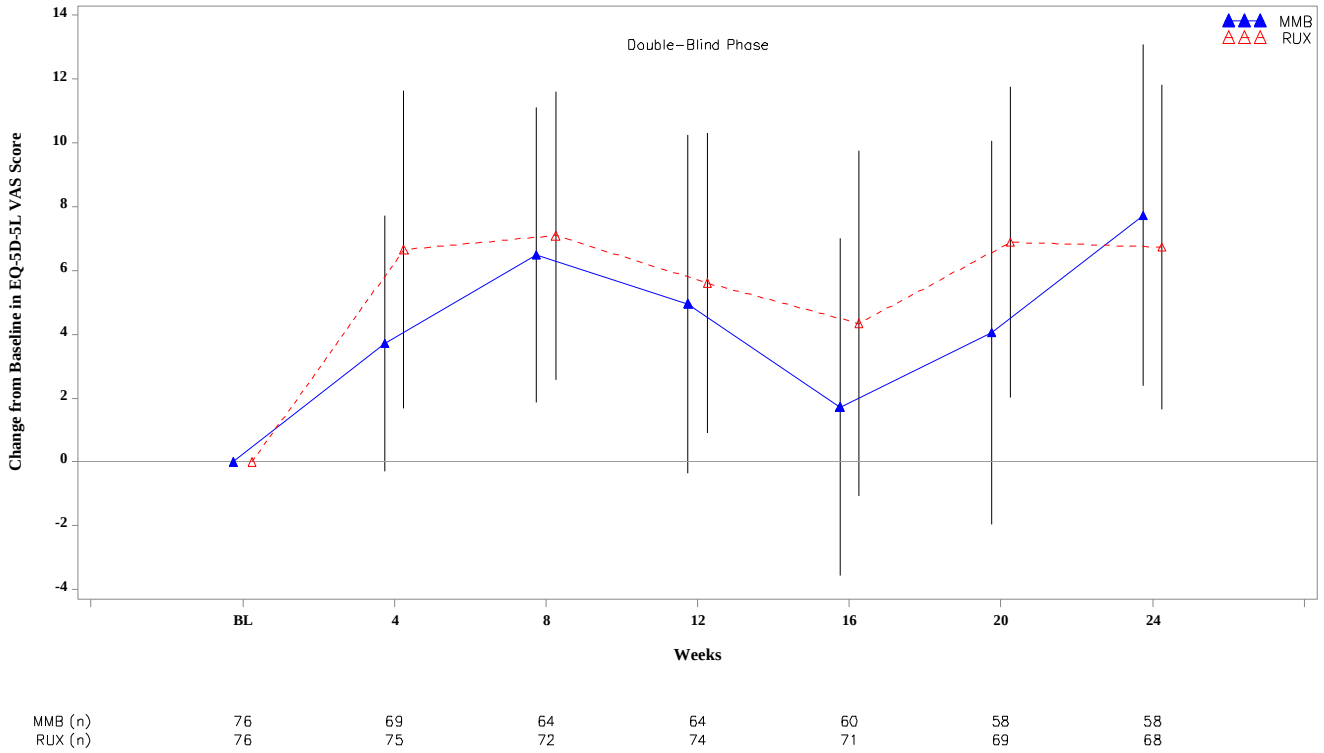
ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-pgic-ext.sas V.03.05 Output file: t-chg-pgic-ext.pdf 29AUG2023: 9:40

1.8 EQ 5D-VAS

GSK Oncology
Study GS-US-352-0101

Figure 2.3901: Mean (incl. 95% CI) Plot of Change From Baseline (including Baseline) in EQ-5D-5L Health State VAS Score Over Time
Double-Blind Phase
ITT-Anemic Analysis Set



MMB (n)	76	69	64	64	60	58	58
RUX (n)	76	75	72	74	71	69	68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 01JUL2019
Source: g-adhoc-line-comb.sas V.03.05 Output file: adhoc-g-eq-line-chg-db.pdf 30AUG2023:12:27

Table 2.6701: Analysis of EQ-5D-5L VAS Score, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Score at Baseline		
n	76	76
Mean (SD)	59.3 (20.42)	55.3 (20.85)
Median	59.0	54.5
Q1, Q3	49.0, 79.0	39.5, 70.0
Min, Max	10.0, 95.0	10.0, 100.0
Return Rate (%)	88%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	88%	81%
Score at Week 4		
n	75	90
Mean (SD)	63.3 (19.43)	62.9 (18.81)
Median	60.0	60.0
Q1, Q3	50.0, 80.0	49.0, 79.0
Min, Max	0.0, 100.0	10.0, 100.0
Return Rate (%)	87%	96%
Number of Subjects in Risk	81	94
Return Rate in Risk (%)	93%	96%
Change in Score at Week 4 from Baseline		
n	69	75
Mean (SD)	3.7 (16.71)	6.7 (21.64)
Median	4.0	9.0
Q1, Q3	-9.0, 13.0	-10.0, 26.0
Min, Max	-40.0, 39.0	-39.0, 49.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
EQ-5D-5L = European Quality of Life 5-Dimension 5-Level (questionnaire).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.6701: Analysis of EQ-5D-5L VAS Score, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	71	76	
n [2]	69	75	
MMRM: Least Squares Mean [SE] (95% CI)	2.73 [2.33] (-1.88, 7.33)	3.68 [2.14] (-0.55, 7.92)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.96 [2.74] (-6.37, 4.45)		
MMRM: P-value	0.73		
Corrected Hedges' g (95% CI)	-0.050 (-0.377, 0.277)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.24		
Percent Change in Score at Week 4 from Baseline			
n	69	75	
Mean (SD)	16.2 (41.53)	28.5 (65.05)	
Median	5.3	15.0	
Q1, Q3	-12.7, 33.3	-14.3, 57.9	
Min, Max	-50.0, 190.0	-79.6, 300.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	71	76	
n [2]	69	75	
MMRM: Least Squares Mean [SE] (95% CI)	10.90 [6.04] (-1.05, 22.84)	17.68 [5.52] (6.76, 28.60)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-6.78 [6.89] (-20.40, 6.83)		
MMRM: P-value	0.33		
Corrected Hedges' g (95% CI)	-0.138 (-0.465, 0.190)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.34		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
EQ-5D-5L = European Quality of Life 5-Dimension 5-Level (questionnaire).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-qre.sas V.03.05 Output file: t-chg-eq-5d-5l-db-gba.pdf 29AUG2023: 9:43

Table 2.6701: Analysis of EQ-5D-5L VAS Score, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Score at Week 8			
n	70	85	
Mean (SD)	66.1 (19.60)	63.2 (18.30)	
Median	69.5	60.0	
Q1, Q3	50.0, 80.0	50.0, 80.0	
Min, Max	11.0, 94.0	20.0, 100.0	
Return Rate (%)	81%	90%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	90%	
Change in Score at Week 8 from Baseline			
n	64	72	
Mean (SD)	6.5 (18.50)	7.1 (19.25)	
Median	8.5	1.0	
Q1, Q3	-4.5, 19.0	-8.5, 21.0	
Min, Max	-31.0, 45.0	-32.0, 60.0	
Difference in Change from Baseline at Week 8			
n [1]	71	76	
n [2]	64	72	
MMRM: Least Squares Mean [SE] (95% CI)	4.78 [2.33] (0.18, 9.38)	3.93 [2.12] (-0.27, 8.13)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.85 [2.72] (-4.53, 6.23)		
MMRM: P-value	0.75		
Corrected Hedges' g (95% CI)	0.046 (-0.290, 0.383)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.74		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
EQ-5D-5L = European Quality of Life 5-Dimension 5-Level (questionnaire).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.6701: Analysis of EQ-5D-5L VAS Score, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Score at Week 8 from Baseline			
n	64	72	
Mean (SD)	21.2 (48.08)	30.2 (76.33)	
Median	10.5	1.9	
Q1, Q3	-5.0, 45.8	-10.2, 49.2	
Min, Max	-73.2, 233.3	-50.0, 500.0	
Difference in Percent Change from Baseline at Week 8			
n [1]	71	76	
n [2]	64	72	
MMRM: Least Squares Mean [SE] (95% CI)	14.24 [7.19] (0.02, 28.46)		18.34 [6.63] (5.24, 31.44)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-4.10 [8.72] (-21.34, 13.14)		
MMRM: P-value	0.64		
Corrected Hedges' g (95% CI)	-0.072 (-0.409, 0.265)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.84		
Score at Week 12			
n	71	89	
Mean (SD)	66.0 (18.02)	61.1 (18.70)	
Median	69.0	59.0	
Q1, Q3	50.0, 80.0	49.0, 76.0	
Min, Max	22.0, 99.0	15.0, 95.0	
Return Rate (%)	83%	95%	
Number of Subjects in Risk	76	94	
Return Rate in Risk (%)	93%	95%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
EQ-5D-5L = European Quality of Life 5-Dimension 5-Level (questionnaire).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.6701: Analysis of EQ-5D-5L VAS Score, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Score at Week 12 from Baseline			
n	64	74	
Mean (SD)	5.0 (21.21)	5.6 (20.31)	
Median	1.5	1.0	
Q1, Q3	-5.0, 18.5	-7.0, 21.0	
Min, Max	-46.0, 60.0	-40.0, 59.0	
Difference in Change from Baseline at Week 12			
n [1]	71	76	
n [2]	64	74	
MMRM: Least Squares Mean [SE] (95% CI)	3.50 [2.44] (-1.34, 8.33)	2.51 [2.22] (-1.88, 6.90)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.98 [2.89] (-4.74, 6.70)		
MMRM: P-value	0.73		
Corrected Hedges' g (95% CI)	0.051 (-0.284, 0.385)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.92		
Percent Change in Score at Week 12 from Baseline			
n	64	74	
Mean (SD)	24.7 (78.42)	24.1 (62.34)	
Median	2.2	2.1	
Q1, Q3	-10.8, 37.8	-9.0, 47.5	
Min, Max	-51.3, 400.0	-50.0, 310.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
EQ-5D-5L = European Quality of Life 5-Dimension 5-Level (questionnaire).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.6701: Analysis of EQ-5D-5L VAS Score, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	71	76	
n [2]	64	74	
MMRM: Least Squares Mean [SE] (95% CI)	18.61 [7.66] (3.47, 33.75)		13.51 [7.03] (-0.38, 27.41)
MMRM: Least Squares Mean Difference [SE] (95% CI)	5.10 [9.40] (-13.49, 23.69)		
MMRM: P-value	0.59		
Corrected Hedges' g (95% CI)	0.083 (-0.251, 0.418)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.77		
Score at Week 16			
n	67	83	
Mean (SD)	61.4 (20.37)	60.9 (20.25)	
Median	65.0	60.0	
Q1, Q3	50.0, 80.0	50.0, 75.0	
Min, Max	0.0, 98.0	0.0, 100.0	
Return Rate (%)	78%	88%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	89%	91%	
Change in Score at Week 16 from Baseline			
n	60	71	
Mean (SD)	1.7 (20.45)	4.3 (22.83)	
Median	0.0	1.0	
Q1, Q3	-11.5, 14.5	-9.0, 19.0	
Min, Max	-51.0, 50.0	-80.0, 64.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
EQ-5D-5L = European Quality of Life 5-Dimension 5-Level (questionnaire).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.6701: Analysis of EQ-5D-5L VAS Score, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	71	76	
n [2]	60	71	
MMRM: Least Squares Mean [SE] (95% CI)	0.01 [2.66] (-5.25, 5.27)	1.85 [2.41] (-2.91, 6.61)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.84 [3.22] (-8.20, 4.52)		
MMRM: P-value	0.57		
Corrected Hedges' g (95% CI)	-0.089 (-0.433, 0.254)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.39		
Percent Change in Score at Week 16 from Baseline			
n	60	71	
Mean (SD)	13.4 (55.28)	23.2 (65.54)	
Median	0.0	2.0	
Q1, Q3	-18.8, 34.5	-13.8, 37.3	
Min, Max	-56.7, 290.0	-100.0, 257.1	
Difference in Percent Change from Baseline at Week 16			
n [1]	71	76	
n [2]	60	71	
MMRM: Least Squares Mean [SE] (95% CI)	7.55 [6.94] (-6.17, 21.27)	14.13 [6.28] (1.70, 26.55)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-6.58 [8.25] (-22.90, 9.74)		
MMRM: P-value	0.43		
Corrected Hedges' g (95% CI)	-0.123 (-0.467, 0.221)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.23		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
EQ-5D-5L = European Quality of Life 5-Dimension 5-Level (questionnaire).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.6701: Analysis of EQ-5D-5L VAS Score, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
Score at Week 20		
n	64	83
Mean (SD)	62.6 (21.99)	63.7 (18.71)
Median	70.0	60.0
Q1, Q3	49.0, 79.5	50.0, 80.0
Min, Max	0.0, 95.0	20.0, 100.0
Return Rate (%)	74%	88%
Number of Subjects in Risk	74	90
Return Rate in Risk (%)	86%	92%
Change in Score at Week 20 from Baseline		
n	58	69
Mean (SD)	4.1 (22.90)	6.9 (20.33)
Median	0.5	1.0
Q1, Q3	-5.0, 15.0	-8.0, 20.0
Min, Max	-70.0, 56.0	-30.0, 66.0
Difference in Change from Baseline at Week 20		
n [1]	71	76
n [2]	58	69
MMRM: Least Squares Mean [SE] (95% CI)	1.25 [2.66] (-4.01, 6.51)	3.95 [2.42] (-0.83, 8.74)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.70 [3.22] (-9.08, 3.67)	
MMRM: P-value	0.40	
Corrected Hedges' g (95% CI)	-0.133 (-0.483, 0.216)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.64	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
EQ-5D-5L = European Quality of Life 5-Dimension 5-Level (questionnaire).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.6701: Analysis of EQ-5D-5L VAS Score, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in Score at Week 20 from Baseline			
n	58	69	
Mean (SD)	19.2 (65.14)	26.5 (64.79)	
Median	0.6	2.6	
Q1, Q3	-8.5, 35.6	-11.1, 33.3	
Min, Max	-79.8, 373.3	-46.7, 300.0	
Difference in Percent Change from Baseline at Week 20			
n [1]	71	76	
n [2]	58	69	
MMRM: Least Squares Mean [SE] (95% CI)	10.44 [7.31] (-4.01, 24.89)	14.82 [6.67] (1.64, 28.00)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-4.38 [8.85] (-21.87, 13.12)		
MMRM: P-value	0.62		
Corrected Hedges' g (95% CI)	-0.078 (-0.428, 0.271)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.55		
Score at Week 24			
n	65	82	
Mean (SD)	68.8 (20.05)	64.2 (18.54)	
Median	73.0	60.5	
Q1, Q3	59.0, 84.0	54.0, 78.0	
Min, Max	2.0, 97.0	11.0, 100.0	
Return Rate (%)	76%	87%	
Number of Subjects in Risk	70	87	
Return Rate in Risk (%)	93%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
EQ-5D-5L = European Quality of Life 5-Dimension 5-Level (questionnaire).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.6701: Analysis of EQ-5D-5L VAS Score, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in Score at Week 24 from Baseline			
n	58	68	
Mean (SD)	7.7 (20.36)	6.7 (21.04)	
Median	5.0	1.5	
Q1, Q3	-4.0, 20.0	-8.0, 21.0	
Min, Max	-64.0, 55.0	-40.0, 55.0	
Difference in Change from Baseline at Week 24			
n [1]	71	76	
n [2]	58	68	
MMRM: Least Squares Mean [SE] (95% CI)	5.40 [2.53] (0.39, 10.40)	3.61 [2.30] (-0.94, 8.16)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.79 [3.02] (-4.19, 7.77)		
MMRM: P-value	0.56		
Corrected Hedges' g (95% CI)	0.093 (-0.258, 0.443)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.73		
Percent Change in Score at Week 24 from Baseline			
n	58	68	
Mean (SD)	22.9 (48.55)	26.6 (64.00)	
Median	6.7	3.9	
Q1, Q3	-4.8, 42.4	-12.8, 51.9	
Min, Max	-76.2, 200.0	-54.2, 300.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
EQ-5D-5L = European Quality of Life 5-Dimension 5-Level (questionnaire).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.6701: Analysis of EQ-5D-5L VAS Score, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	71	76	
n [2]	58	68	
MMRM: Least Squares Mean [SE] (95% CI)	16.61 [6.45] (3.86, 29.36)		17.25 [5.85] (5.68, 28.82)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.64 [7.49] (-15.45, 14.18)		
MMRM: P-value	0.93		
Corrected Hedges' g (95% CI)	-0.013 (-0.363, 0.337)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.82		

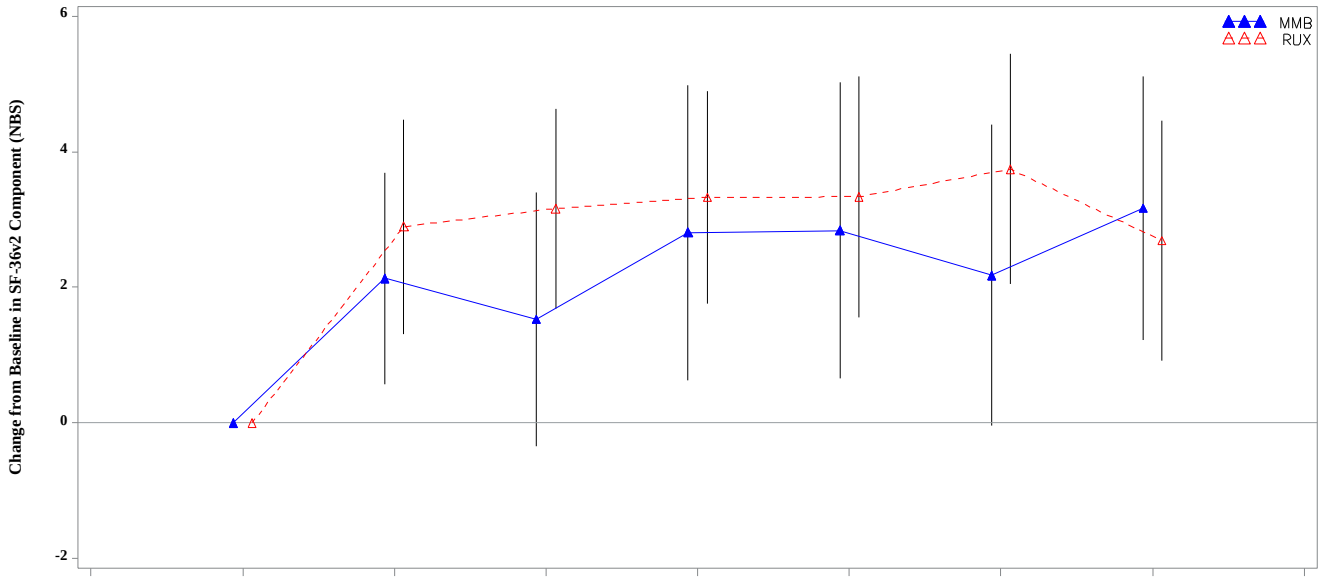
ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
EQ-5D-5L = European Quality of Life 5-Dimension 5-Level (questionnaire).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

1.9 SF36 v2

GSK Oncology
Study GS-US-352-0101

Figure 2.4001: Mean (incl. 95% CI) Plots of Change From Baseline (including Baseline) in SF-36v2 (for PCS, MCS and each of 8 domains)
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=SF3602-Physical Functioning: NBS



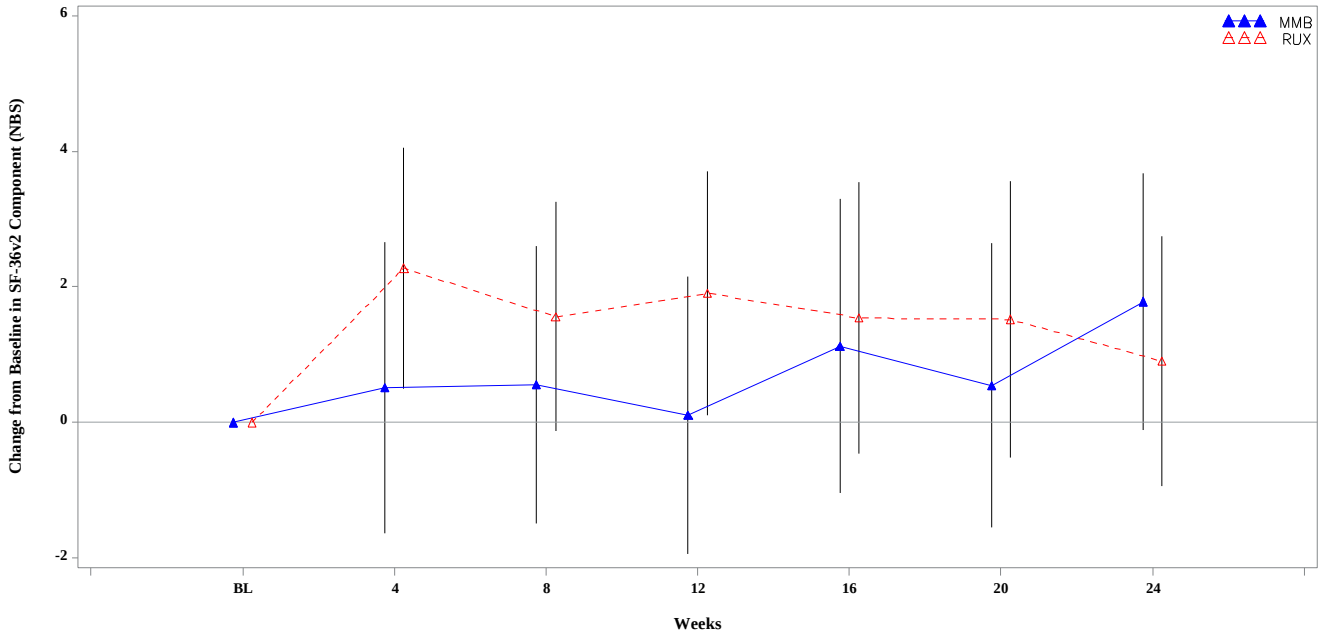
MMB (n)	77	70	65	64	60	58	58
RUX (n)	76	74	72	73	70	68	67

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 01JUL2019
Source: g-adhoc-line-comb.sas V.03.05 Output file: adhoc-g-sf-line-chg-db.pdf 30AUG2023:12:27

Figure 2.4001: Mean (incl. 95% CI) Plots of Change From Baseline (including Baseline) in SF-36v2 (for PCS, MCS and each of 8 domains)
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=SF3602-Role Physical: NBS



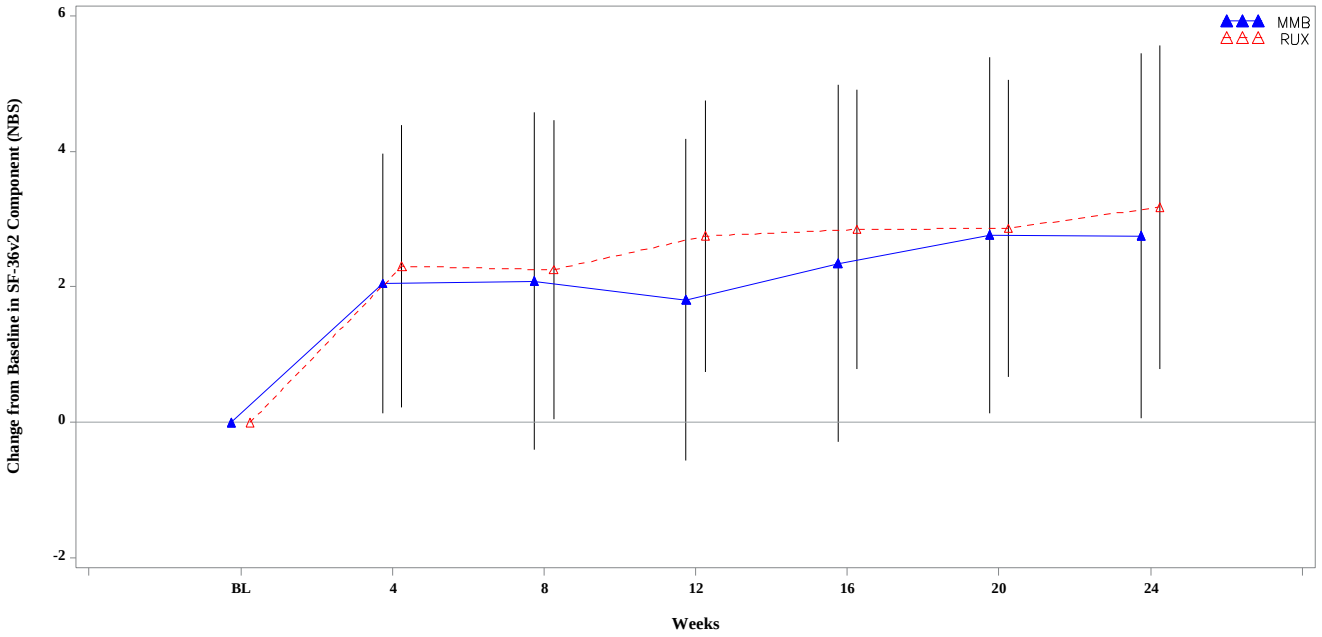
MMB (n)	77	70	65	64	60	58	58
RUX (n)	76	74	72	73	70	68	67

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 01JUL2019
Source: g-adhoc-line-comb.sas V.03.05 Output file: adhoc-g-sf-line-chg-db.pdf 30AUG2023:12:27

Figure 2.4001: Mean (incl. 95% CI) Plots of Change From Baseline (including Baseline) in SF-36v2 (for PCS, MCS and each of 8 domains)
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=SF3602-Bodily Pain: NBS



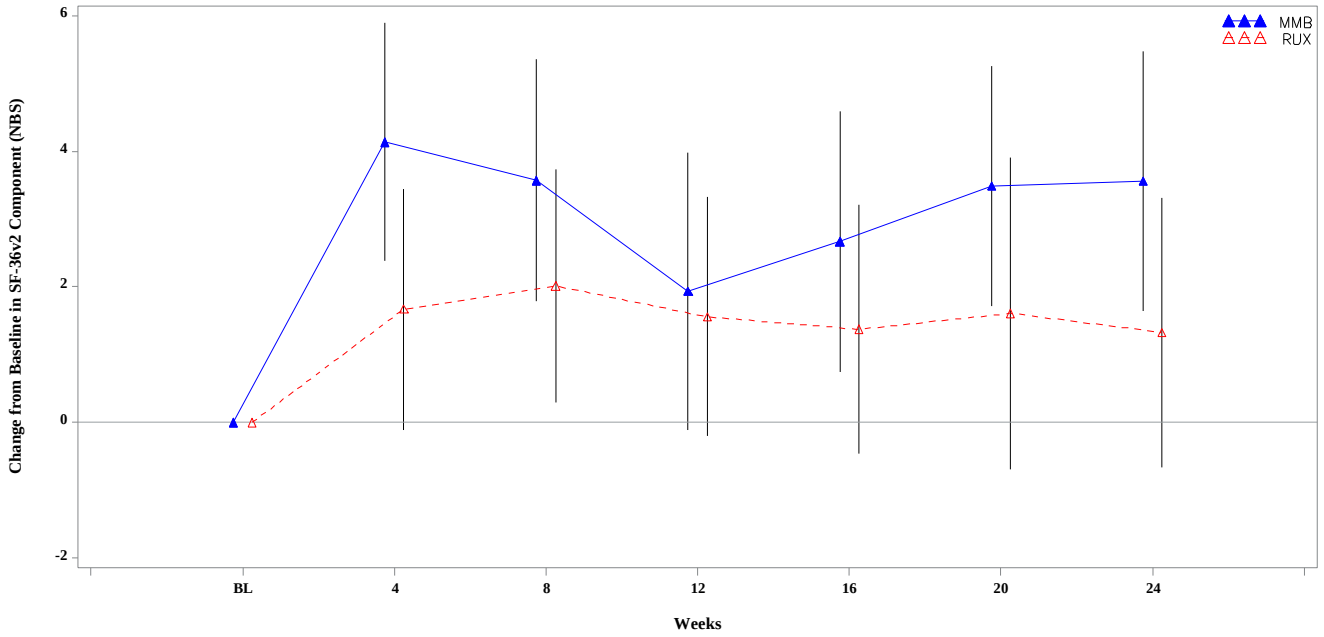
MMB (n)	77	70	65	64	60	58	58
RUX (n)	76	74	72	73	70	68	67

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 01JUL2019
Source: g-adhoc-line-comb.sas V.03.05 Output file: adhoc-g-sf-line-chg-db.pdf 30AUG2023:12:27

Figure 2.4001: Mean (incl. 95% CI) Plots of Change From Baseline (including Baseline) in SF-36v2 (for PCS, MCS and each of 8 domains)
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=SF3602-General Health: NBS



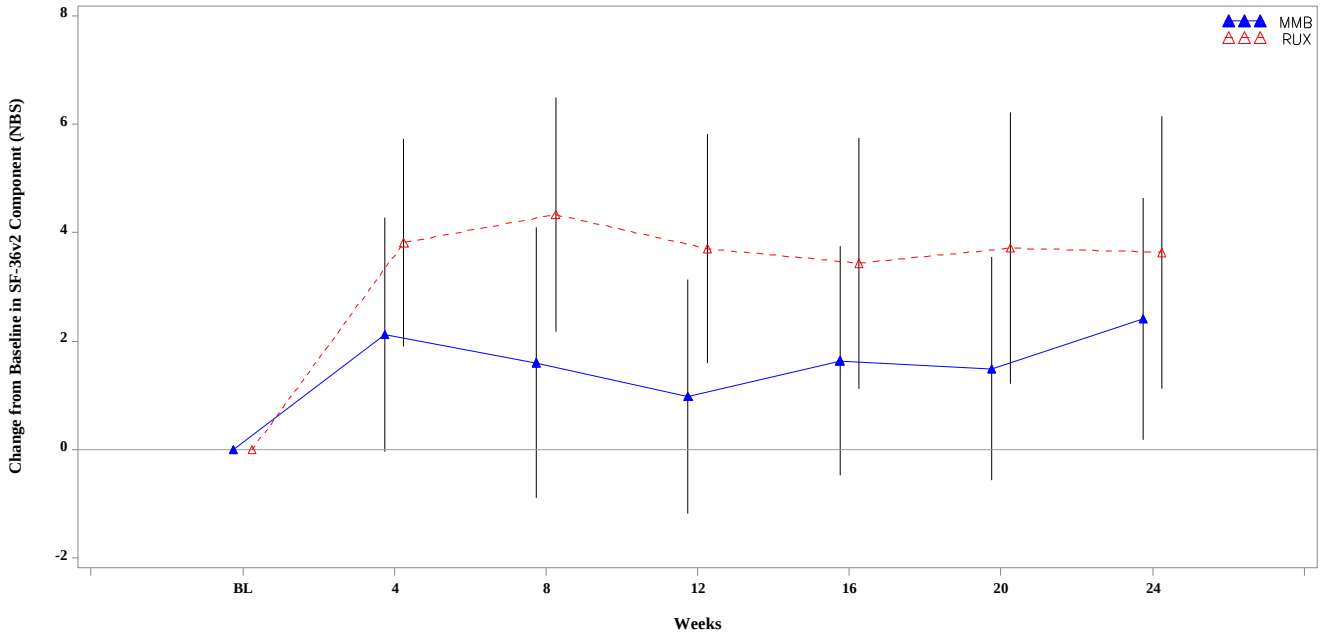
MMB (n)	77	70	65	64	60	58	58
RUX (n)	76	74	72	73	70	68	67

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 01JUL2019
Source: g-adhoc-line-comb.sas V.03.05 Output file: adhoc-g-sf-line-chg-db.pdf 30AUG2023:12:27

Figure 2.4001: Mean (incl. 95% CI) Plots of Change From Baseline (including Baseline) in SF-36v2 (for PCS, MCS and each of 8 domains)
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=SF3602-Vitality: NBS



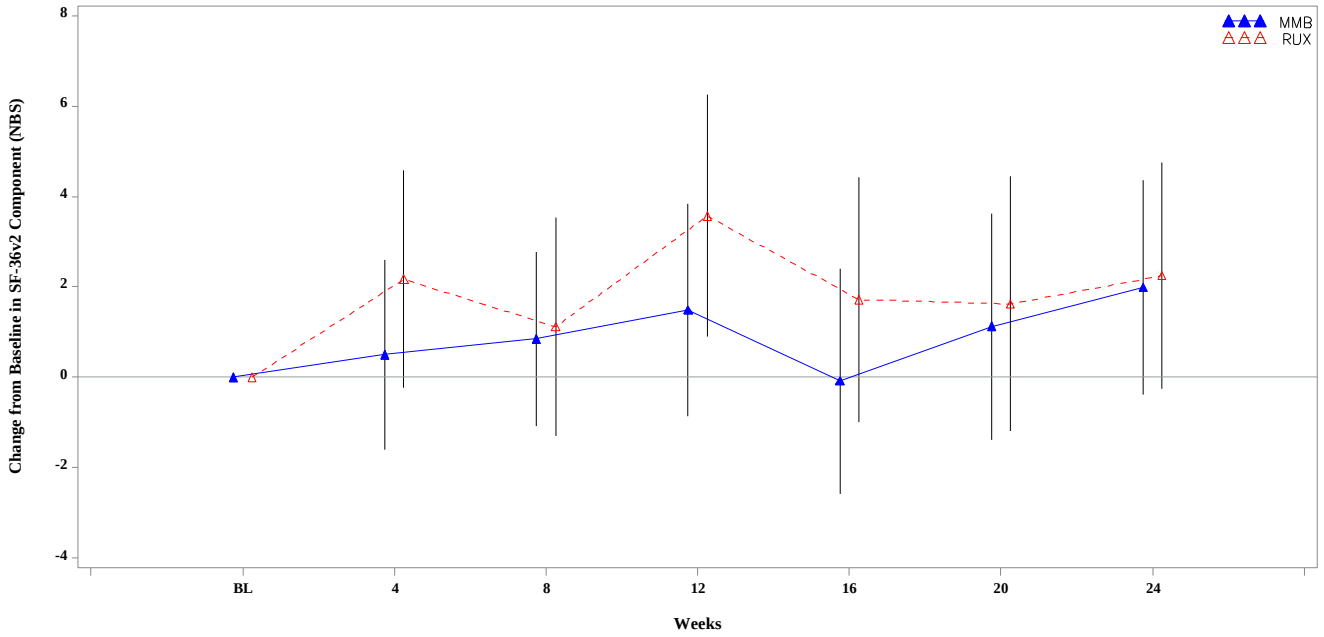
MMB (n)	77	70	65	64	60	58	58
RUX (n)	76	74	72	73	70	68	67

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 01JUL2019
Source: g-adhoc-line-comb.sas V.03.05 Output file: adhoc-g-sf-line-chg-db.pdf 30AUG2023:12:27

Figure 2.4001: Mean (incl. 95% CI) Plots of Change From Baseline (including Baseline) in SF-36v2 (for PCS, MCS and each of 8 domains)
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=SF3602-Social Functioning: NBS



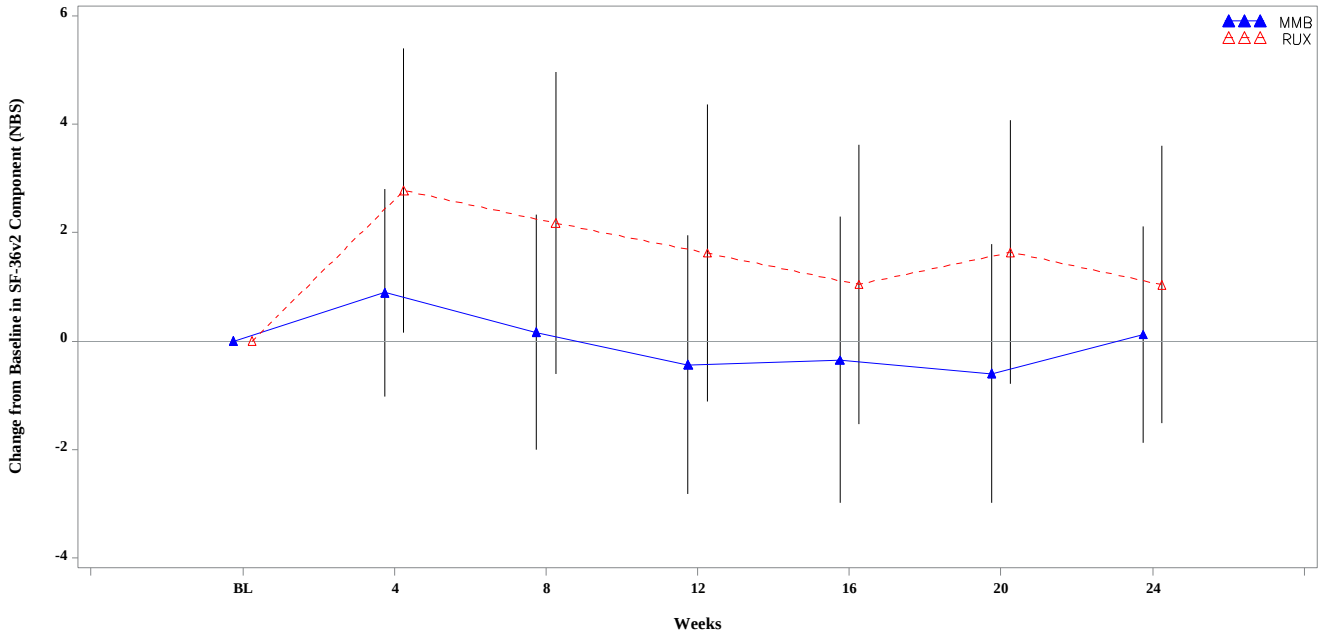
MMB (n)	77	70	65	64	60	58	58
RUX (n)	76	74	72	73	70	68	67

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 01JUL2019
Source: g-adhoc-line-comb.sas V.03.05 Output file: adhoc-g-sf-line-chg-db.pdf 30AUG2023:12:27

Figure 2.4001: Mean (incl. 95% CI) Plots of Change From Baseline (including Baseline) in SF-36v2 (for PCS, MCS and each of 8 domains)
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=SF3602-Role Emotional: NBS



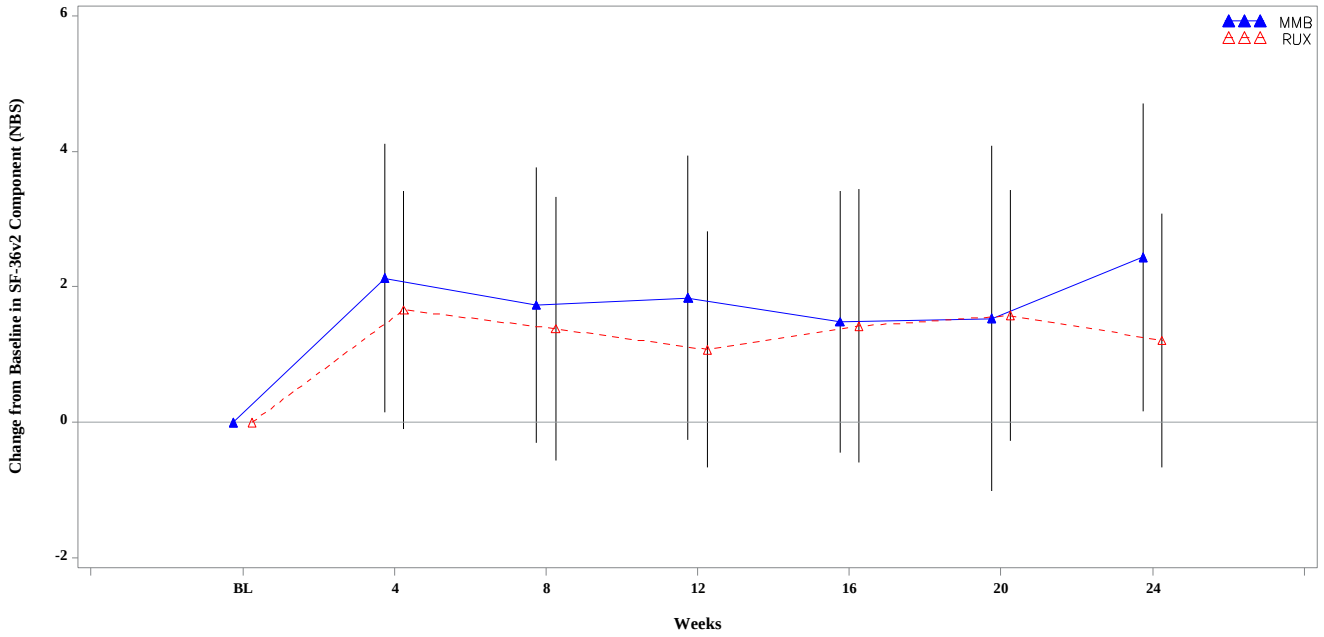
MMB (n)	77	70	65	64	60	58	58
RUX (n)	76	74	72	73	70	68	67

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 01JUL2019
Source: g-adhoc-line-comb.sas V.03.05 Output file: adhoc-g-sf-line-chg-db.pdf 30AUG2023:12:27

Figure 2.4001: Mean (incl. 95% CI) Plots of Change From Baseline (including Baseline) in SF-36v2 (for PCS, MCS and each of 8 domains)
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=SF3602-Mental Health: NBS



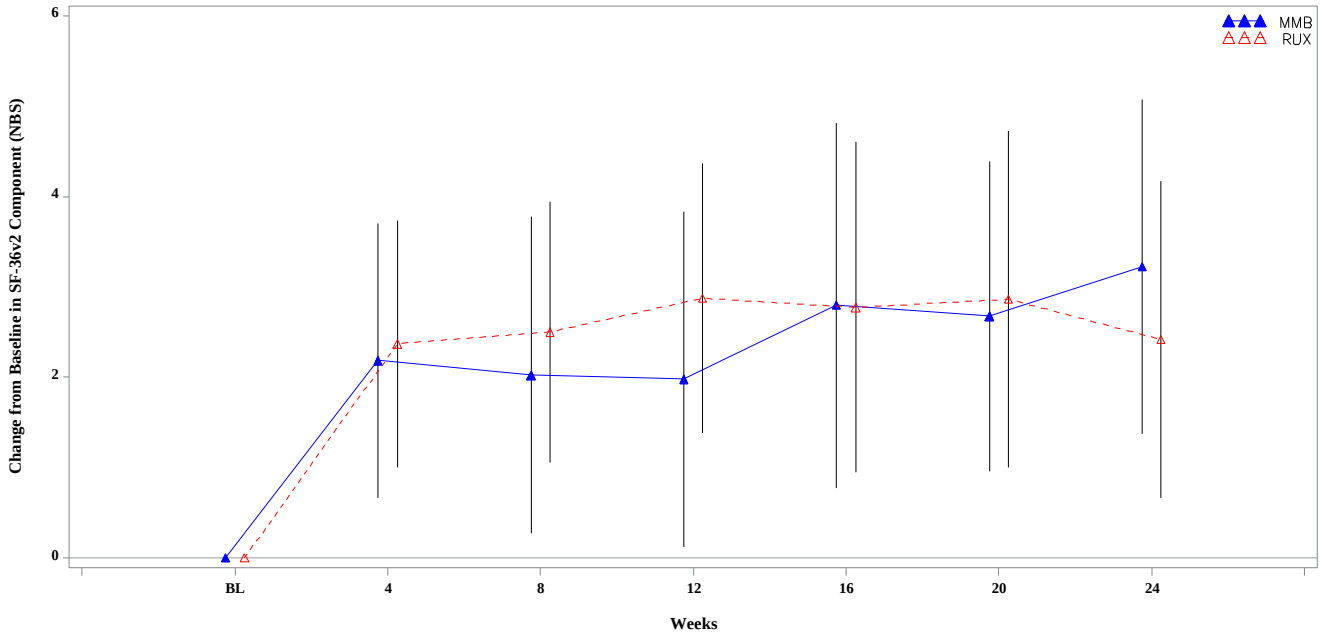
MMB (n)	77	70	65	64	60	58	58
RUX (n)	76	74	72	73	70	68	67

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 01JUL2019
Source: g-adhoc-line-comb.sas V.03.05 Output file: adhoc-g-sf-line-chg-db.pdf 30AUG2023:12:27

Figure 2.4001: Mean (incl. 95% CI) Plots of Change From Baseline (including Baseline) in SF-36v2 (for PCS, MCS and each of 8 domains)
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=SF3602-Physical Component Summary



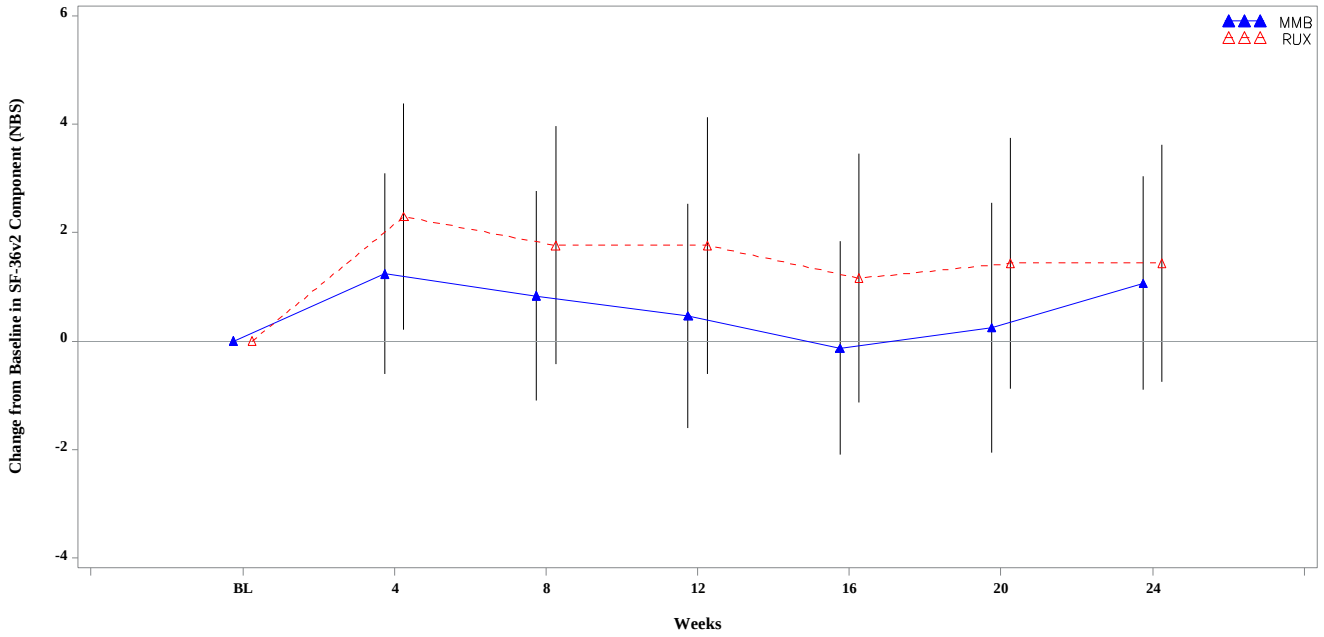
MMB (n)	77	70	65	64	60	58	58
RUX (n)	76	74	72	73	70	68	67

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 01JUL2019
Source: g-adhoc-line-comb.sas V.03.05 Output file: adhoc-g-sf-line-chg-db.pdf 30AUG2023:12:27

Figure 2.4001: Mean (incl. 95% CI) Plots of Change From Baseline (including Baseline) in SF-36v2 (for PCS, MCS and each of 8 domains)
Double-Blind Phase
ITT-Anemic Analysis Set

Parameter=SF3602-Mental Component Summary



MMB (n)	77	70	65	64	60	58	58
RUX (n)	76	74	72	73	70	68	67

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 01JUL2019
Source: g-adhoc-line-comb.sas V.03.05 Output file: adhoc-g-sf-line-chg-db.pdf 30AUG2023:12:27

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
SF3602-Physical Functioning: NBS at Baseline		
n	77	76
Mean (SD)	38.8 (9.86)	37.9 (11.16)
Median	40.3	36.5
Q1, Q3	30.8, 48.0	28.8, 49.9
Min, Max	19.3, 57.5	19.3, 55.6
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
SF3602-Physical Functioning: NBS at Week 4		
n	75	89
Mean (SD)	41.8 (9.49)	41.3 (10.33)
Median	42.2	40.3
Q1, Q3	34.6, 49.9	34.6, 51.8
Min, Max	21.2, 57.5	19.3, 57.5
Return Rate (%)	87%	95%
Number of Subjects in Risk	81	94
Return Rate in Risk (%)	93%	95%
Change in SF3602-Physical Functioning: NBS at Week 4 from Baseline		
n	70	74
Mean (SD)	2.1 (6.56)	2.9 (6.82)
Median	1.9	1.9
Q1, Q3	0.0, 5.7	-1.9, 5.7
Min, Max	-19.1, 17.2	-11.5, 26.8

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	72	76	
n [2]	70	74	
MMRM: Least Squares Mean [SE] (95% CI)	2.06 [0.85] (0.38, 3.75)	2.58 [0.82] (0.96, 4.20)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.52 [1.05] (-2.60, 1.56)		
MMRM: P-value	0.62		
Corrected Hedges' g (95% CI)	-0.073 (-0.400, 0.254)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.95		
Percent Change in SF3602-Physical Functioning: NBS at Week 4 from Baseline			
n	70	74	
Mean (SD)	7.2 (17.70)	11.0 (25.89)	
Median	6.7	3.7	
Q1, Q3	0.0, 17.6	-3.6, 18.1	
Min, Max	-38.4, 52.7	-35.2, 107.1	
Difference in Percent Change from Baseline at Week 4			
n [1]	72	76	
n [2]	70	74	
MMRM: Least Squares Mean [SE] (95% CI)	6.77 [2.70] (1.43, 12.10)	9.31 [2.60] (4.17, 14.45)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.55 [3.38] (-9.23, 4.14)		
MMRM: P-value	0.45		
Corrected Hedges' g (95% CI)	-0.113 (-0.440, 0.214)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.98		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
SF3602-Physical Functioning: NBS at Week 8			
n	70	85	
Mean (SD)	41.0 (9.49)	41.7 (10.19)	
Median	42.2	42.2	
Q1, Q3	34.6, 48.0	34.6, 49.9	
Min, Max	19.3, 57.5	19.3, 57.5	
Return Rate (%)	81%	90%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	90%	
Change in SF3602-Physical Functioning: NBS at Week 8 from Baseline			
n	65	72	
Mean (SD)	1.5 (7.54)	3.2 (6.25)	
Median	1.9	1.9	
Q1, Q3	-1.9, 5.7	-1.0, 7.7	
Min, Max	-21.1, 19.1	-9.6, 28.7	
Difference in Change from Baseline at Week 8			
n [1]	72	76	
n [2]	65	72	
MMRM: Least Squares Mean [SE] (95% CI)	1.25 [0.87] (-0.47, 2.97)	2.85 [0.83] (1.21, 4.48)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.60 [1.07] (-3.72, 0.52)		
MMRM: P-value	0.14		
Corrected Hedges' g (95% CI)	-0.227 (-0.563, 0.109)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.24		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in SF3602-Physical Functioning: NBS at Week 8 from Baseline			
n	65	72	
Mean (SD)	6.3 (21.21)	11.1 (20.91)	
Median	4.1	5.2	
Q1, Q3	-4.5, 18.1	-1.7, 24.9	
Min, Max	-36.6, 71.1	-27.7, 114.8	
Difference in Percent Change from Baseline at Week 8			
n [1]	72	76	
n [2]	65	72	
MMRM: Least Squares Mean [SE] (95% CI)	5.15 [2.57] (0.06, 10.23)	9.42 [2.44] (4.60, 14.25)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-4.28 [3.15] (-10.50, 1.95)		
MMRM: P-value	0.18		
Corrected Hedges' g (95% CI)	-0.205 (-0.542, 0.131)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.32		
SF3602-Physical Functioning: NBS at Week 12			
n	70	88	
Mean (SD)	42.7 (8.84)	41.7 (10.55)	
Median	42.2	42.2	
Q1, Q3	36.5, 49.9	34.6, 51.8	
Min, Max	21.2, 57.5	19.3, 57.5	
Return Rate (%)	81%	94%	
Number of Subjects in Risk	76	94	
Return Rate in Risk (%)	92%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in SF3602-Physical Functioning: NBS at Week 12 from Baseline			
n	64	73	
Mean (SD)	2.8 (8.72)	3.3 (6.72)	
Median	3.8	1.9	
Q1, Q3	-1.9, 7.7	-1.9, 5.7	
Min, Max	-23.0, 23.0	-15.3, 28.7	
Difference in Change from Baseline at Week 12			
n [1]	72	76	
n [2]	64	73	
MMRM: Least Squares Mean [SE] (95% CI)	2.66 [0.94] (0.80, 4.52)		2.93 [0.89] (1.18, 4.69)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.27 [1.18] (-2.60, 2.06)		
MMRM: P-value	0.82		
Corrected Hedges' g (95% CI)	-0.035 (-0.371, 0.300)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.97		
Percent Change in SF3602-Physical Functioning: NBS at Week 12 from Baseline			
n	64	73	
Mean (SD)	10.5 (24.89)	12.0 (23.93)	
Median	8.3	7.4	
Q1, Q3	-4.6, 23.6	-3.5, 19.9	
Min, Max	-52.0, 85.3	-44.3, 114.8	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	72	76	
n [2]	64	73	
MMRM: Least Squares Mean [SE] (95% CI)	9.57 [2.84] (3.95, 15.19)		10.06 [2.69] (4.74, 15.38)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.49 [3.56] (-7.53, 6.55)		
MMRM: P-value	0.89		
Corrected Hedges' g (95% CI)	-0.021 (-0.357, 0.315)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.81		
SF3602-Physical Functioning: NBS at Week 16			
n	66	82	
Mean (SD)	42.7 (10.00)	42.2 (10.61)	
Median	43.2	44.2	
Q1, Q3	36.5, 49.9	34.6, 51.8	
Min, Max	21.2, 57.5	21.2, 57.5	
Return Rate (%)	77%	87%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	88%	90%	
Change in SF3602-Physical Functioning: NBS at Week 16 from Baseline			
n	60	70	
Mean (SD)	2.8 (8.45)	3.3 (7.46)	
Median	3.8	3.8	
Q1, Q3	-1.9, 7.7	0.0, 7.7	
Min, Max	-17.2, 23.0	-19.1, 24.9	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	72	76	
n [2]	60	70	
MMRM: Least Squares Mean [SE] (95% CI)	2.19 [1.01] (0.19, 4.19)		3.14 [0.95] (1.25, 5.02)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.95 [1.28] (-3.48, 1.59)		
MMRM: P-value	0.46		
Corrected Hedges' g (95% CI)	-0.119 (-0.464, 0.226)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.74		
Percent Change in SF3602-Physical Functioning: NBS at Week 16 from Baseline			
n	60	70	
Mean (SD)	9.8 (24.80)	11.9 (24.89)	
Median	9.3	8.1	
Q1, Q3	-4.7, 20.0	0.0, 26.6	
Min, Max	-39.0, 66.4	-47.5, 99.4	
Difference in Percent Change from Baseline at Week 16			
n [1]	72	76	
n [2]	60	70	
MMRM: Least Squares Mean [SE] (95% CI)	7.81 [2.99] (1.90, 13.72)		10.73 [2.82] (5.15, 16.31)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.92 [3.78] (-10.39, 4.55)		
MMRM: P-value	0.44		
Corrected Hedges' g (95% CI)	-0.124 (-0.469, 0.221)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.72		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
SF3602-Physical Functioning: NBS at Week 20		
n	63	82
Mean (SD)	41.9 (10.05)	42.7 (10.72)
Median	44.2	42.2
Q1, Q3	34.6, 49.9	36.5, 51.8
Min, Max	21.2, 57.5	19.3, 57.5
Return Rate (%)	73%	87%
Number of Subjects in Risk	74	90
Return Rate in Risk (%)	85%	91%
Change in SF3602-Physical Functioning: NBS at Week 20 from Baseline		
n	58	68
Mean (SD)	2.2 (8.45)	3.7 (7.00)
Median	1.9	3.8
Q1, Q3	-3.8, 5.7	0.0, 7.7
Min, Max	-26.8, 23.0	-15.3, 28.7
Difference in Change from Baseline at Week 20		
n [1]	72	76
n [2]	58	68
MMRM: Least Squares Mean [SE] (95% CI)	1.69 [1.00] (-0.28, 3.66)	3.40 [0.94] (1.54, 5.25)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.71 [1.26] (-4.20, 0.79)	
MMRM: P-value	0.18	
Corrected Hedges' g (95% CI)	-0.221 (-0.572, 0.131)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.31	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in SF3602-Physical Functioning: NBS at Week 20 from Baseline			
n	58	68	
Mean (SD)	7.9 (24.70)	12.6 (24.31)	
Median	4.4	7.5	
Q1, Q3	-7.1, 17.6	0.0, 23.9	
Min, Max	-55.8, 85.3	-38.0, 114.8	
Difference in Percent Change from Baseline at Week 20			
n [1]	72	76	
n [2]	58	68	
MMRM: Least Squares Mean [SE] (95% CI)	6.56 [3.02] (0.59, 12.54)		11.00 [2.84] (5.37, 16.62)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-4.43 [3.82] (-11.98, 3.12)		
MMRM: P-value	0.25		
Corrected Hedges' g (95% CI)	-0.189 (-0.541, 0.162)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.30		
SF3602-Physical Functioning: NBS at Week 24			
n	64	81	
Mean (SD)	43.2 (8.87)	42.8 (10.50)	
Median	44.2	44.2	
Q1, Q3	38.4, 49.9	34.6, 51.8	
Min, Max	23.1, 57.5	19.3, 57.5	
Return Rate (%)	74%	86%	
Number of Subjects in Risk	70	87	
Return Rate in Risk (%)	91%	93%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in SF3602-Physical Functioning: NBS at Week 24 from Baseline			
n	58	67	
Mean (SD)	3.2 (7.40)	2.7 (7.25)	
Median	3.8	1.9	
Q1, Q3	0.0, 5.7	-1.9, 7.7	
Min, Max	-17.2, 19.1	-17.2, 19.1	
Difference in Change from Baseline at Week 24			
n [1]	72	76	
n [2]	58	67	
MMRM: Least Squares Mean [SE] (95% CI)	2.68 [0.95] (0.80, 4.57)	2.44 [0.90] (0.66, 4.22)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.24 [1.20] (-2.12, 2.61)		
MMRM: P-value	0.84		
Corrected Hedges' g (95% CI)	0.033 (-0.318, 0.385)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.81		
Percent Change in SF3602-Physical Functioning: NBS at Week 24 from Baseline			
n	58	67	
Mean (SD)	10.7 (22.77)	9.6 (22.56)	
Median	8.3	5.6	
Q1, Q3	0.0, 17.6	-3.8, 21.0	
Min, Max	-33.3, 71.1	-42.7, 59.7	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	72	76	
n [2]	58	67	
MMRM: Least Squares Mean [SE] (95% CI)	9.34 [2.81] (3.79, 14.89)		8.30 [2.65] (3.07, 13.54)
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.04 [3.50] (-5.89, 7.96)		
MMRM: P-value	0.77		
Corrected Hedges' g (95% CI)	0.048 (-0.304, 0.399)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.78		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
SF3602-Role Physical: NBS at Baseline		
n	77	76
Mean (SD)	38.6 (9.64)	38.5 (10.53)
Median	39.2	38.1
Q1, Q3	30.2, 45.9	30.2, 45.9
Min, Max	21.2, 57.2	21.2, 57.2
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
SF3602-Role Physical: NBS at Week 4		
n	75	89
Mean (SD)	39.9 (9.03)	41.0 (9.45)
Median	39.2	39.2
Q1, Q3	32.5, 45.9	34.7, 48.2
Min, Max	21.2, 57.2	21.2, 57.2
Return Rate (%)	87%	95%
Number of Subjects in Risk	81	94
Return Rate in Risk (%)	93%	95%
Change in SF3602-Role Physical: NBS at Week 4 from Baseline		
n	70	74
Mean (SD)	0.5 (9.02)	2.3 (7.65)
Median	2.2	2.2
Q1, Q3	-4.5, 6.7	-2.3, 6.7
Min, Max	-24.7, 27.0	-18.0, 22.5

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	72	76	
n [2]	70	74	
MMRM: Least Squares Mean [SE] (95% CI)	-0.16 [0.95] (-2.04, 1.73)	1.67 [0.91] (-0.13, 3.48)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.83 [1.20] (-4.19, 0.54)		
MMRM: P-value	0.13		
Corrected Hedges' g (95% CI)	-0.230 (-0.558, 0.098)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.34		
Percent Change in SF3602-Role Physical: NBS at Week 4 from Baseline			
n	70	74	
Mean (SD)	4.5 (24.55)	9.4 (22.84)	
Median	4.6	4.6	
Q1, Q3	-12.3, 16.1	-4.9, 22.3	
Min, Max	-51.3, 96.4	-31.4, 74.3	
Difference in Percent Change from Baseline at Week 4			
n [1]	72	76	
n [2]	70	74	
MMRM: Least Squares Mean [SE] (95% CI)	1.92 [2.66] (-3.33, 7.17)	6.98 [2.55] (1.94, 12.02)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-5.06 [3.34] (-11.67, 1.55)		
MMRM: P-value	0.13		
Corrected Hedges' g (95% CI)	-0.228 (-0.556, 0.100)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.28		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
SF3602-Role Physical: NBS at Week 8			
n	70	85	
Mean (SD)	40.2 (8.78)	40.4 (9.39)	
Median	39.2	39.2	
Q1, Q3	32.5, 48.2	32.5, 48.2	
Min, Max	21.2, 57.2	21.2, 57.2	
Return Rate (%)	81%	90%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	90%	
Change in SF3602-Role Physical: NBS at Week 8 from Baseline			
n	65	72	
Mean (SD)	0.6 (8.26)	1.6 (7.19)	
Median	0.0	0.0	
Q1, Q3	-6.7, 6.7	-2.3, 4.5	
Min, Max	-15.7, 20.2	-13.5, 27.0	
Difference in Change from Baseline at Week 8			
n [1]	72	76	
n [2]	65	72	
MMRM: Least Squares Mean [SE] (95% CI)	-0.06 [0.93] (-1.91, 1.79)	0.92 [0.88] (-0.82, 2.67)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.98 [1.16] (-3.27, 1.31)		
MMRM: P-value	0.40		
Corrected Hedges' g (95% CI)	-0.130 (-0.466, 0.206)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.91		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-qre.sas V.03.05 Output file: t-chg-sf-36v2-db-gba.pdf 29AUG2023: 9:42

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in SF3602-Role Physical: NBS at Week 8 from Baseline			
n	65	72	
Mean (SD)	4.7 (23.27)	7.2 (23.93)	
Median	0.0	0.0	
Q1, Q3	-15.7, 17.5	-7.0, 14.9	
Min, Max	-34.2, 86.1	-28.7, 89.2	
Difference in Percent Change from Baseline at Week 8			
n [1]	72	76	
n [2]	65	72	
MMRM: Least Squares Mean [SE] (95% CI)	2.44 [2.78] (-3.05, 7.93)	4.65 [2.63] (-0.56, 9.85)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.20 [3.50] (-9.12, 4.72)		
MMRM: P-value	0.53		
Corrected Hedges' g (95% CI)	-0.098 (-0.434, 0.238)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.66		
SF3602-Role Physical: NBS at Week 12			
n	70	88	
Mean (SD)	39.7 (8.05)	40.2 (9.77)	
Median	39.2	39.2	
Q1, Q3	34.7, 43.7	32.5, 48.2	
Min, Max	21.2, 57.2	21.2, 57.2	
Return Rate (%)	81%	94%	
Number of Subjects in Risk	76	94	
Return Rate in Risk (%)	92%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in SF3602-Role Physical: NBS at Week 12 from Baseline			
n	64	73	
Mean (SD)	0.1 (8.21)	1.9 (7.72)	
Median	0.0	0.0	
Q1, Q3	-4.5, 5.6	-4.5, 6.7	
Min, Max	-24.7, 18.0	-24.7, 27.0	
Difference in Change from Baseline at Week 12			
n [1]	72	76	
n [2]	64	73	
MMRM: Least Squares Mean [SE] (95% CI)	-0.37 [0.93] (-2.21, 1.47)	1.17 [0.88] (-0.57, 2.90)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.54 [1.15] (-3.81, 0.74)		
MMRM: P-value	0.18		
Corrected Hedges' g (95% CI)	-0.204 (-0.541, 0.132)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.24		
Percent Change in SF3602-Role Physical: NBS at Week 12 from Baseline			
n	64	73	
Mean (SD)	3.4 (21.76)	7.8 (22.79)	
Median	0.0	0.0	
Q1, Q3	-11.1, 16.1	-7.9, 19.1	
Min, Max	-51.3, 67.0	-49.0, 89.2	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	72	76	
n [2]	64	73	
MMRM: Least Squares Mean [SE] (95% CI)	1.35 [2.57] (-3.73, 6.42)		5.08 [2.41] (0.31, 9.84)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-3.73 [3.17] (-10.00, 2.54)		
MMRM: P-value	0.24		
Corrected Hedges' g (95% CI)	-0.180 (-0.517, 0.156)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.30		
SF3602-Role Physical: NBS at Week 16			
n	66	82	
Mean (SD)	40.5 (9.32)	40.5 (9.76)	
Median	39.2	39.2	
Q1, Q3	34.7, 48.2	32.5, 48.2	
Min, Max	21.2, 57.2	21.2, 57.2	
Return Rate (%)	77%	87%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	88%	90%	
Change in SF3602-Role Physical: NBS at Week 16 from Baseline			
n	60	70	
Mean (SD)	1.1 (8.40)	1.5 (8.42)	
Median	0.0	0.0	
Q1, Q3	-4.5, 6.7	-2.2, 6.7	
Min, Max	-20.2, 22.5	-26.9, 27.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	72	76	
n [2]	60	70	
MMRM: Least Squares Mean [SE] (95% CI)	0.46 [1.03] (-1.58, 2.50)		0.83 [0.97] (-1.08, 2.74)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.36 [1.30] (-2.93, 2.20)		
MMRM: P-value	0.78		
Corrected Hedges' g (95% CI)	-0.045 (-0.390, 0.300)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.43		
Percent Change in SF3602-Role Physical: NBS at Week 16 from Baseline			
n	60	70	
Mean (SD)	5.1 (22.19)	6.7 (23.71)	
Median	0.0	0.0	
Q1, Q3	-10.4, 19.5	-5.7, 16.2	
Min, Max	-42.0, 67.0	-55.9, 89.2	
Difference in Percent Change from Baseline at Week 16			
n [1]	72	76	
n [2]	60	70	
MMRM: Least Squares Mean [SE] (95% CI)	2.81 [2.80] (-2.72, 8.34)		4.08 [2.62] (-1.09, 9.25)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.27 [3.51] (-8.20, 5.67)		
MMRM: P-value	0.72		
Corrected Hedges' g (95% CI)	-0.058 (-0.403, 0.287)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.43		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
SF3602-Role Physical: NBS at Week 20			
n	63	82	
Mean (SD)	39.3 (8.91)	41.1 (9.64)	
Median	39.2	40.3	
Q1, Q3	32.5, 43.7	34.7, 48.2	
Min, Max	21.2, 57.2	21.2, 57.2	
Return Rate (%)	73%	87%	
Number of Subjects in Risk	74	90	
Return Rate in Risk (%)	85%	91%	
Change in SF3602-Role Physical: NBS at Week 20 from Baseline			
n	58	68	
Mean (SD)	0.5 (7.97)	1.5 (8.41)	
Median	0.0	1.1	
Q1, Q3	-4.5, 6.7	-2.2, 6.7	
Min, Max	-18.0, 20.2	-27.0, 20.2	
Difference in Change from Baseline at Week 20			
n [1]	72	76	
n [2]	58	68	
MMRM: Least Squares Mean [SE] (95% CI)	-0.44 [1.00] (-2.43, 1.54)	1.04 [0.94] (-0.82, 2.89)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.48 [1.25] (-3.96, 1.00)		
MMRM: P-value	0.24		
Corrected Hedges' g (95% CI)	-0.191 (-0.542, 0.160)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.36		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-qre.sas V.03.05 Output file: t-chg-sf-36v2-db-gba.pdf 29AUG2023: 9:42

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in SF3602-Role Physical: NBS at Week 20 from Baseline			
n	58	68	
Mean (SD)	3.7 (22.63)	6.8 (23.65)	
Median	0.0	2.0	
Q1, Q3	-11.8, 20.7	-4.8, 21.5	
Min, Max	-37.3, 86.1	-53.5, 66.9	
Difference in Percent Change from Baseline at Week 20			
n [1]	72	76	
n [2]	58	68	
MMRM: Least Squares Mean [SE] (95% CI)	0.42 [2.73] (-4.98, 5.82)		4.69 [2.56] (-0.37, 9.75)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-4.27 [3.41] (-11.02, 2.47)		
MMRM: P-value	0.21		
Corrected Hedges' g (95% CI)	-0.203 (-0.554, 0.149)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.30		
SF3602-Role Physical: NBS at Week 24			
n	64	81	
Mean (SD)	40.8 (7.93)	40.7 (9.24)	
Median	39.2	39.2	
Q1, Q3	34.7, 47.1	34.7, 48.2	
Min, Max	21.2, 57.2	21.2, 57.2	
Return Rate (%)	74%	86%	
Number of Subjects in Risk	70	87	
Return Rate in Risk (%)	91%	93%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in SF3602-Role Physical: NBS at Week 24 from Baseline			
n	58	67	
Mean (SD)	1.8 (7.20)	0.9 (7.56)	
Median	1.1	0.0	
Q1, Q3	-2.3, 6.7	-2.3, 6.7	
Min, Max	-13.5, 15.7	-20.2, 20.2	
Difference in Change from Baseline at Week 24			
n [1]	72	76	
n [2]	58	67	
MMRM: Least Squares Mean [SE] (95% CI)	0.80 [0.91] (-0.99, 2.59)	0.12 [0.85] (-1.56, 1.81)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.68 [1.11] (-1.52, 2.87)		
MMRM: P-value	0.54		
Corrected Hedges' g (95% CI)	0.097 (-0.255, 0.449)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.74		
Percent Change in SF3602-Role Physical: NBS at Week 24 from Baseline			
n	58	67	
Mean (SD)	7.3 (20.26)	5.2 (22.22)	
Median	2.4	0.0	
Q1, Q3	-6.9, 20.7	-7.4, 19.1	
Min, Max	-25.7, 52.0	-42.0, 84.6	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	72	76	
n [2]	58	67	
MMRM: Least Squares Mean [SE] (95% CI)	3.98 [2.53] (-1.02, 8.98)		2.23 [2.38] (-2.47, 6.93)
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.75 [3.11] (-4.40, 7.90)		
MMRM: P-value	0.58		
Corrected Hedges' g (95% CI)	0.090 (-0.262, 0.441)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.82		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
SF3602-Bodily Pain: NBS at Baseline		
n	77	76
Mean (SD)	46.5 (11.52)	46.7 (11.70)
Median	46.7	46.7
Q1, Q3	38.2, 55.6	38.2, 62.0
Min, Max	21.7, 62.0	25.7, 62.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
SF3602-Bodily Pain: NBS at Week 4		
n	75	89
Mean (SD)	48.9 (10.16)	48.6 (9.19)
Median	50.7	47.5
Q1, Q3	38.2, 55.6	42.2, 55.6
Min, Max	21.7, 62.0	30.1, 62.0
Return Rate (%)	87%	95%
Number of Subjects in Risk	81	94
Return Rate in Risk (%)	93%	95%
Change in SF3602-Bodily Pain: NBS at Week 4 from Baseline		
n	70	74
Mean (SD)	2.1 (8.01)	2.3 (9.01)
Median	0.0	2.0
Q1, Q3	-0.8, 7.7	0.0, 8.1
Min, Max	-16.1, 23.8	-17.3, 31.5

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	72	76	
n [2]	70	74	
MMRM: Least Squares Mean [SE] (95% CI)	1.85 [0.94] (-0.02, 3.71)	2.21 [0.90] (0.42, 3.99)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.36 [1.18] (-2.70, 1.98)		
MMRM: P-value	0.76		
Corrected Hedges' g (95% CI)	-0.046 (-0.372, 0.281)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.56		
Percent Change in SF3602-Bodily Pain: NBS at Week 4 from Baseline			
n	70	74	
Mean (SD)	6.8 (20.10)	8.8 (24.09)	
Median	0.0	3.9	
Q1, Q3	-1.6, 19.0	0.0, 20.1	
Min, Max	-34.6, 68.6	-34.3, 102.9	
Difference in Percent Change from Baseline at Week 4			
n [1]	72	76	
n [2]	70	74	
MMRM: Least Squares Mean [SE] (95% CI)	7.02 [2.41] (2.25, 11.79)	9.21 [2.31] (4.65, 13.77)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.19 [3.02] (-8.16, 3.79)		
MMRM: P-value	0.47		
Corrected Hedges' g (95% CI)	-0.109 (-0.436, 0.218)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.56		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
SF3602-Bodily Pain: NBS at Week 8			
n	70	85	
Mean (SD)	48.6 (10.40)	48.9 (9.36)	
Median	48.7	50.7	
Q1, Q3	42.2, 55.6	42.6, 55.6	
Min, Max	21.7, 62.0	30.1, 62.0	
Return Rate (%)	81%	90%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	90%	
Change in SF3602-Bodily Pain: NBS at Week 8 from Baseline			
n	65	72	
Mean (SD)	2.1 (10.05)	2.3 (9.39)	
Median	0.0	0.0	
Q1, Q3	0.0, 8.1	-4.0, 8.1	
Min, Max	-31.5, 35.5	-23.8, 31.5	
Difference in Change from Baseline at Week 8			
n [1]	72	76	
n [2]	65	72	
MMRM: Least Squares Mean [SE] (95% CI)	1.47 [1.08] (-0.67, 3.61)	2.17 [1.02] (0.15, 4.18)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.70 [1.38] (-3.43, 2.03)		
MMRM: P-value	0.61		
Corrected Hedges' g (95% CI)	-0.080 (-0.415, 0.256)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.82		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in SF3602-Bodily Pain: NBS at Week 8 from Baseline			
n	65	72	
Mean (SD)	8.0 (26.75)	8.7 (25.01)	
Median	0.0	0.0	
Q1, Q3	0.0, 21.9	-9.0, 22.0	
Min, Max	-50.7, 133.8	-38.4, 102.9	
Difference in Percent Change from Baseline at Week 8			
n [1]	72	76	
n [2]	65	72	
MMRM: Least Squares Mean [SE] (95% CI)	7.35 [2.81] (1.80, 12.89)		9.20 [2.64] (3.98, 14.43)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.86 [3.58] (-8.94, 5.23)		
MMRM: P-value	0.60		
Corrected Hedges' g (95% CI)	-0.082 (-0.418, 0.253)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.98		
SF3602-Bodily Pain: NBS at Week 12			
n	70	88	
Mean (SD)	48.7 (9.87)	48.8 (9.38)	
Median	51.1	49.1	
Q1, Q3	38.2, 55.6	42.6, 55.6	
Min, Max	30.6, 62.0	21.7, 62.0	
Return Rate (%)	81%	94%	
Number of Subjects in Risk	76	94	
Return Rate in Risk (%)	92%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in SF3602-Bodily Pain: NBS at Week 12 from Baseline			
n	64	73	
Mean (SD)	1.8 (9.51)	2.8 (8.59)	
Median	0.0	0.0	
Q1, Q3	-3.2, 8.5	0.0, 8.1	
Min, Max	-23.8, 23.8	-16.5, 31.5	
Difference in Change from Baseline at Week 12			
n [1]	72	76	
n [2]	64	73	
MMRM: Least Squares Mean [SE] (95% CI)	1.82 [1.02] (-0.21, 3.85)	2.72 [0.95] (0.83, 4.60)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.90 [1.29] (-3.44, 1.65)		
MMRM: P-value	0.49		
Corrected Hedges' g (95% CI)	-0.109 (-0.445, 0.227)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.78		
Percent Change in SF3602-Bodily Pain: NBS at Week 12 from Baseline			
n	64	73	
Mean (SD)	6.9 (22.52)	9.5 (23.05)	
Median	0.0	0.0	
Q1, Q3	-6.6, 21.4	0.0, 20.4	
Min, Max	-40.7, 68.6	-43.3, 102.9	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	72	76	
n [2]	64	73	
MMRM: Least Squares Mean [SE] (95% CI)	7.87 [2.53] (2.87, 12.86)		10.10 [2.35] (5.45, 14.74)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.23 [3.15] (-8.45, 3.99)		
MMRM: P-value	0.48		
Corrected Hedges' g (95% CI)	-0.110 (-0.446, 0.226)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.63		
SF3602-Bodily Pain: NBS at Week 16			
n	66	82	
Mean (SD)	49.1 (10.06)	49.3 (9.57)	
Median	51.5	49.1	
Q1, Q3	38.2, 62.0	42.6, 55.6	
Min, Max	30.6, 62.0	26.5, 62.0	
Return Rate (%)	77%	87%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	88%	90%	
Change in SF3602-Bodily Pain: NBS at Week 16 from Baseline			
n	60	70	
Mean (SD)	2.3 (10.18)	2.8 (8.65)	
Median	0.0	1.8	
Q1, Q3	-4.0, 7.7	-4.0, 8.5	
Min, Max	-23.8, 31.5	-19.4, 25.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	72	76	
n [2]	60	70	
MMRM: Least Squares Mean [SE] (95% CI)	1.92 [1.07] (-0.20, 4.04)		2.60 [1.00] (0.62, 4.57)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.68 [1.36] (-3.37, 2.01)		
MMRM: P-value	0.62		
Corrected Hedges' g (95% CI)	-0.081 (-0.426, 0.264)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.72		
Percent Change in SF3602-Bodily Pain: NBS at Week 16 from Baseline			
n	60	70	
Mean (SD)	8.6 (25.87)	9.5 (22.54)	
Median	0.0	3.9	
Q1, Q3	-9.4, 21.2	-7.8, 20.8	
Min, Max	-38.4, 102.9	-31.2, 81.8	
Difference in Percent Change from Baseline at Week 16			
n [1]	72	76	
n [2]	60	70	
MMRM: Least Squares Mean [SE] (95% CI)	8.64 [2.71] (3.29, 13.99)		9.45 [2.51] (4.48, 14.42)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.81 [3.41] (-7.55, 5.93)		
MMRM: P-value	0.81		
Corrected Hedges' g (95% CI)	-0.038 (-0.383, 0.306)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.77		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
SF3602-Bodily Pain: NBS at Week 20		
n	63	82
Mean (SD)	49.1 (10.41)	48.6 (9.76)
Median	51.5	50.3
Q1, Q3	42.2, 55.6	38.2, 55.6
Min, Max	21.7, 62.0	26.5, 62.0
Return Rate (%)	73%	87%
Number of Subjects in Risk	74	90
Return Rate in Risk (%)	85%	91%
Change in SF3602-Bodily Pain: NBS at Week 20 from Baseline		
n	58	68
Mean (SD)	2.8 (9.99)	2.9 (9.07)
Median	0.0	0.0
Q1, Q3	0.0, 8.9	0.0, 8.5
Min, Max	-21.0, 25.0	-23.8, 31.5
Difference in Change from Baseline at Week 20		
n [1]	72	76
n [2]	58	68
MMRM: Least Squares Mean [SE] (95% CI)	2.35 [1.11] (0.15, 4.56)	2.54 [1.04] (0.50, 4.59)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.19 [1.42] (-2.99, 2.62)	
MMRM: P-value	0.89	
Corrected Hedges' g (95% CI)	-0.022 (-0.372, 0.328)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	1.00	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-qre.sas V.03.05 Output file: t-chg-sf-36v2-db-gba.pdf 29AUG2023: 9:42

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in SF3602-Bodily Pain: NBS at Week 20 from Baseline			
n	58	68	
Mean (SD)	8.8 (24.31)	9.8 (24.89)	
Median	0.0	0.0	
Q1, Q3	0.0, 20.4	0.0, 21.9	
Min, Max	-40.7, 81.8	-38.4, 102.9	
Difference in Percent Change from Baseline at Week 20			
n [1]	72	76	
n [2]	58	68	
MMRM: Least Squares Mean [SE] (95% CI)	9.12 [2.83] (3.52, 14.73)		9.66 [2.63] (4.45, 14.86)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.54 [3.60] (-7.65, 6.58)		
MMRM: P-value	0.88		
Corrected Hedges' g (95% CI)	-0.025 (-0.375, 0.326)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.79		
SF3602-Bodily Pain: NBS at Week 24			
n	64	81	
Mean (SD)	49.8 (9.48)	50.0 (10.67)	
Median	50.7	51.5	
Q1, Q3	42.2, 62.0	42.2, 62.0	
Min, Max	21.7, 62.0	26.5, 62.0	
Return Rate (%)	74%	86%	
Number of Subjects in Risk	70	87	
Return Rate in Risk (%)	91%	93%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in SF3602-Bodily Pain: NBS at Week 24 from Baseline			
n	58	67	
Mean (SD)	2.8 (10.25)	3.2 (9.78)	
Median	0.0	0.0	
Q1, Q3	-4.0, 7.7	0.0, 8.1	
Min, Max	-23.8, 31.5	-17.3, 31.9	
Difference in Change from Baseline at Week 24			
n [1]	72	76	
n [2]	58	67	
MMRM: Least Squares Mean [SE] (95% CI)	2.57 [1.18] (0.24, 4.89)	3.08 [1.10] (0.91, 5.25)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.51 [1.51] (-3.51, 2.48)		
MMRM: P-value	0.73		
Corrected Hedges' g (95% CI)	-0.057 (-0.409, 0.295)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.87		
Percent Change in SF3602-Bodily Pain: NBS at Week 24 from Baseline			
n	58	67	
Mean (SD)	9.5 (26.38)	10.2 (26.97)	
Median	0.0	0.0	
Q1, Q3	-7.3, 21.9	0.0, 20.4	
Min, Max	-38.4, 102.9	-33.6, 105.7	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	72	76	
n [2]	58	67	
MMRM: Least Squares Mean [SE] (95% CI)	9.90 [3.13] (3.70, 16.09)		10.52 [2.92] (4.74, 16.30)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.62 [4.04] (-8.61, 7.37)		
MMRM: P-value	0.88		
Corrected Hedges' g (95% CI)	-0.026 (-0.377, 0.326)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.91		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
SF3602-General Health: NBS at Baseline		
n	77	76
Mean (SD)	39.9 (7.94)	40.4 (8.42)
Median	40.4	40.4
Q1, Q3	33.2, 43.7	35.6, 45.6
Min, Max	23.7, 64.1	19.0, 62.7
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
SF3602-General Health: NBS at Week 4		
n	75	89
Mean (SD)	44.2 (9.63)	42.0 (8.39)
Median	46.1	41.3
Q1, Q3	38.0, 50.8	35.6, 46.1
Min, Max	19.0, 66.5	26.1, 66.5
Return Rate (%)	87%	95%
Number of Subjects in Risk	81	94
Return Rate in Risk (%)	93%	95%
Change in SF3602-General Health: NBS at Week 4 from Baseline		
n	70	74
Mean (SD)	4.1 (7.35)	1.7 (7.67)
Median	2.9	0.0
Q1, Q3	0.0, 9.5	-2.4, 5.7
Min, Max	-10.5, 22.8	-15.2, 28.5

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	72	76	
n [2]	70	74	
MMRM: Least Squares Mean [SE] (95% CI)	3.62 [0.95] (1.74, 5.50)	1.37 [0.91] (-0.42, 3.16)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	2.26 [1.17] (-0.06, 4.57)		
MMRM: P-value	0.057		
Corrected Hedges' g (95% CI)	0.285 (-0.044, 0.613)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.15		
Percent Change in SF3602-General Health: NBS at Week 4 from Baseline			
n	70	74	
Mean (SD)	11.8 (20.13)	6.4 (21.27)	
Median	8.5	0.0	
Q1, Q3	0.0, 24.4	-6.3, 16.0	
Min, Max	-28.6, 69.4	-35.4, 78.1	
Difference in Percent Change from Baseline at Week 4			
n [1]	72	76	
n [2]	70	74	
MMRM: Least Squares Mean [SE] (95% CI)	10.16 [2.54] (5.14, 15.17)	5.31 [2.42] (0.53, 10.09)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	4.85 [3.11] (-1.30, 10.99)		
MMRM: P-value	0.12		
Corrected Hedges' g (95% CI)	0.230 (-0.098, 0.557)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.15		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
SF3602-General Health: NBS at Week 8			
n	70	85	
Mean (SD)	43.5 (8.91)	42.2 (9.09)	
Median	43.7	41.3	
Q1, Q3	38.0, 49.9	35.6, 48.4	
Min, Max	23.7, 65.1	21.3, 60.3	
Return Rate (%)	81%	90%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	90%	
Change in SF3602-General Health: NBS at Week 8 from Baseline			
n	65	72	
Mean (SD)	3.6 (7.21)	2.0 (7.30)	
Median	4.8	0.5	
Q1, Q3	0.0, 7.1	-2.9, 5.7	
Min, Max	-12.8, 22.4	-10.5, 20.0	
Difference in Change from Baseline at Week 8			
n [1]	72	76	
n [2]	65	72	
MMRM: Least Squares Mean [SE] (95% CI)	2.91 [0.95] (1.02, 4.80)	1.78 [0.90] (0.00, 3.55)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.13 [1.17] (-1.18, 3.44)		
MMRM: P-value	0.33		
Corrected Hedges' g (95% CI)	0.147 (-0.189, 0.483)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.14		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in SF3602-General Health: NBS at Week 8 from Baseline			
n	65	72	
Mean (SD)	10.6 (19.56)	6.8 (20.49)	
Median	11.8	1.3	
Q1, Q3	0.0, 18.3	-6.9, 17.3	
Min, Max	-29.4, 60.1	-22.3, 76.6	
Difference in Percent Change from Baseline at Week 8			
n [1]	72	76	
n [2]	65	72	
MMRM: Least Squares Mean [SE] (95% CI)	8.50 [2.56] (3.43, 13.57)		5.78 [2.41] (1.01, 10.55)
MMRM: Least Squares Mean Difference [SE] (95% CI)	2.71 [3.13] (-3.47, 8.89)		
MMRM: P-value	0.39		
Corrected Hedges' g (95% CI)	0.131 (-0.204, 0.467)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.090		
SF3602-General Health: NBS at Week 12			
n	70	88	
Mean (SD)	42.5 (7.89)	41.7 (8.29)	
Median	40.8	41.3	
Q1, Q3	38.0, 48.4	35.6, 48.4	
Min, Max	26.1, 60.3	21.3, 62.7	
Return Rate (%)	81%	94%	
Number of Subjects in Risk	76	94	
Return Rate in Risk (%)	92%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in SF3602-General Health: NBS at Week 12 from Baseline			
n	64	73	
Mean (SD)	1.9 (8.18)	1.6 (7.56)	
Median	2.4	0.0	
Q1, Q3	-4.3, 7.6	-3.3, 5.7	
Min, Max	-15.2, 18.1	-14.3, 26.2	
Difference in Change from Baseline at Week 12			
n [1]	72	76	
n [2]	64	73	
MMRM: Least Squares Mean [SE] (95% CI)	1.11 [0.97] (-0.81, 3.03)		1.36 [0.91] (-0.43, 3.15)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.25 [1.19] (-2.60, 2.10)		
MMRM: P-value	0.84		
Corrected Hedges' g (95% CI)	-0.032 (-0.367, 0.304)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.64		
Percent Change in SF3602-General Health: NBS at Week 12 from Baseline			
n	64	73	
Mean (SD)	7.1 (21.82)	6.2 (21.83)	
Median	6.1	0.0	
Q1, Q3	-8.5, 20.7	-8.5, 16.3	
Min, Max	-33.4, 53.5	-31.3, 85.7	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	72	76	
n [2]	64	73	
MMRM: Least Squares Mean [SE] (95% CI)	4.46 [2.63] (-0.74, 9.65)		5.54 [2.46] (0.67, 10.40)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.08 [3.22] (-7.44, 5.28)		
MMRM: P-value	0.74		
Corrected Hedges' g (95% CI)	-0.051 (-0.387, 0.285)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.69		
SF3602-General Health: NBS at Week 16			
n	66	82	
Mean (SD)	43.1 (8.46)	41.9 (9.43)	
Median	41.3	41.3	
Q1, Q3	38.0, 48.4	35.6, 48.4	
Min, Max	26.1, 66.5	19.0, 65.1	
Return Rate (%)	77%	87%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	88%	90%	
Change in SF3602-General Health: NBS at Week 16 from Baseline			
n	60	70	
Mean (SD)	2.7 (7.45)	1.4 (7.68)	
Median	2.4	0.0	
Q1, Q3	-2.4, 7.6	-2.4, 5.7	
Min, Max	-17.6, 25.2	-15.2, 29.5	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	72	76	
n [2]	60	70	
MMRM: Least Squares Mean [SE] (95% CI)	1.59 [1.04] (-0.47, 3.65)		1.40 [0.98] (-0.53, 3.33)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.19 [1.30] (-2.37, 2.76)		
MMRM: P-value	0.88		
Corrected Hedges' g (95% CI)	0.024 (-0.321, 0.369)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.37		
Percent Change in SF3602-General Health: NBS at Week 16 from Baseline			
n	60	70	
Mean (SD)	8.3 (19.91)	5.2 (20.63)	
Median	6.0	0.0	
Q1, Q3	-5.1, 18.3	-6.7, 15.0	
Min, Max	-36.3, 61.0	-26.3, 82.8	
Difference in Percent Change from Baseline at Week 16			
n [1]	72	76	
n [2]	60	70	
MMRM: Least Squares Mean [SE] (95% CI)	5.27 [2.73] (-0.12, 10.67)		4.75 [2.56] (-0.30, 9.80)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.52 [3.37] (-6.14, 7.18)		
MMRM: P-value	0.88		
Corrected Hedges' g (95% CI)	0.024 (-0.320, 0.369)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.35		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
SF3602-General Health: NBS at Week 20			
n	63	82	
Mean (SD)	43.3 (8.14)	41.9 (8.82)	
Median	41.3	42.0	
Q1, Q3	38.0, 46.1	36.5, 48.4	
Min, Max	28.5, 65.1	19.0, 66.5	
Return Rate (%)	73%	87%	
Number of Subjects in Risk	74	90	
Return Rate in Risk (%)	85%	91%	
Change in SF3602-General Health: NBS at Week 20 from Baseline			
n	58	68	
Mean (SD)	3.5 (6.72)	1.6 (9.52)	
Median	2.4	0.0	
Q1, Q3	0.0, 7.1	-4.8, 6.4	
Min, Max	-9.5, 23.8	-14.3, 30.0	
Difference in Change from Baseline at Week 20			
n [1]	72	76	
n [2]	58	68	
MMRM: Least Squares Mean [SE] (95% CI)	1.73 [1.05] (-0.36, 3.81)	1.29 [0.99] (-0.66, 3.24)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.43 [1.32] (-2.17, 3.04)		
MMRM: P-value	0.74		
Corrected Hedges' g (95% CI)	0.053 (-0.297, 0.404)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.058		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in SF3602-General Health: NBS at Week 20 from Baseline			
n	58	68	
Mean (SD)	10.3 (18.07)	6.8 (27.35)	
Median	7.8	0.0	
Q1, Q3	0.0, 18.7	-12.7, 16.3	
Min, Max	-22.3, 57.6	-40.4, 103.9	
Difference in Percent Change from Baseline at Week 20			
n [1]	72	76	
n [2]	58	68	
MMRM: Least Squares Mean [SE] (95% CI)	5.33 [2.89] (-0.38, 11.03)		5.54 [2.70] (0.21, 10.88)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.22 [3.60] (-7.34, 6.91)		
MMRM: P-value	0.95		
Corrected Hedges' g (95% CI)	-0.010 (-0.360, 0.341)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.065		
SF3602-General Health: NBS at Week 24			
n	64	81	
Mean (SD)	43.8 (7.84)	42.2 (9.19)	
Median	43.2	42.7	
Q1, Q3	38.4, 48.4	36.5, 48.4	
Min, Max	23.7, 66.5	19.0, 64.1	
Return Rate (%)	74%	86%	
Number of Subjects in Risk	70	87	
Return Rate in Risk (%)	91%	93%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in SF3602-General Health: NBS at Week 24 from Baseline			
n	58	67	
Mean (SD)	3.6 (7.31)	1.3 (8.14)	
Median	2.4	1.0	
Q1, Q3	-1.4, 8.1	-4.8, 7.1	
Min, Max	-12.8, 25.2	-17.6, 20.5	
Difference in Change from Baseline at Week 24			
n [1]	72	76	
n [2]	58	67	
MMRM: Least Squares Mean [SE] (95% CI)	2.09 [0.98] (0.15, 4.04)	0.76 [0.92] (-1.06, 2.59)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.33 [1.21] (-1.07, 3.72)		
MMRM: P-value	0.27		
Corrected Hedges' g (95% CI)	0.175 (-0.177, 0.528)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.24		
Percent Change in SF3602-General Health: NBS at Week 24 from Baseline			
n	58	67	
Mean (SD)	11.0 (20.34)	5.3 (22.78)	
Median	5.2	2.2	
Q1, Q3	-3.1, 23.0	-10.0, 18.3	
Min, Max	-26.5, 70.2	-48.1, 67.5	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	72	76	
n [2]	58	67	
MMRM: Least Squares Mean [SE] (95% CI)	6.84 [2.68] (1.55, 12.13)		3.51 [2.51] (-1.45, 8.47)
MMRM: Least Squares Mean Difference [SE] (95% CI)	3.33 [3.29] (-3.18, 9.84)		
MMRM: P-value	0.31		
Corrected Hedges' g (95% CI)	0.162 (-0.190, 0.514)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.16		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
SF3602-Vitality: NBS at Baseline		
n	77	76
Mean (SD)	44.1 (11.08)	43.3 (11.40)
Median	43.7	43.7
Q1, Q3	34.8, 52.6	34.8, 49.6
Min, Max	22.9, 64.5	22.9, 70.4
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
SF3602-Vitality: NBS at Week 4		
n	75	89
Mean (SD)	46.8 (9.54)	47.3 (9.62)
Median	46.7	46.7
Q1, Q3	40.7, 52.6	40.7, 52.6
Min, Max	25.9, 70.4	22.9, 70.4
Return Rate (%)	87%	95%
Number of Subjects in Risk	81	94
Return Rate in Risk (%)	93%	95%
Change in SF3602-Vitality: NBS at Week 4 from Baseline		
n	70	74
Mean (SD)	2.1 (9.04)	3.8 (8.30)
Median	1.5	3.0
Q1, Q3	-3.0, 6.0	0.0, 8.9
Min, Max	-17.8, 23.8	-20.8, 23.8

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	72	76	
n [2]	70	74	
MMRM: Least Squares Mean [SE] (95% CI)	1.20 [0.99] (-0.75, 3.16)	2.81 [0.95] (0.94, 4.69)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.61 [1.22] (-4.02, 0.81)		
MMRM: P-value	0.19		
Corrected Hedges' g (95% CI)	-0.195 (-0.522, 0.133)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.15		
Percent Change in SF3602-Vitality: NBS at Week 4 from Baseline			
n	70	74	
Mean (SD)	8.3 (24.94)	12.4 (24.35)	
Median	2.3	6.8	
Q1, Q3	-6.8, 15.8	0.0, 23.6	
Min, Max	-32.1, 103.8	-34.2, 91.9	
Difference in Percent Change from Baseline at Week 4			
n [1]	72	76	
n [2]	70	74	
MMRM: Least Squares Mean [SE] (95% CI)	5.39 [2.73] (0.00, 10.78)	8.91 [2.62] (3.74, 14.08)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-3.52 [3.35] (-10.13, 3.10)		
MMRM: P-value	0.29		
Corrected Hedges' g (95% CI)	-0.155 (-0.482, 0.173)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.15		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
SF3602-Vitality: NBS at Week 8			
n	70	85	
Mean (SD)	46.3 (10.57)	47.8 (9.19)	
Median	46.7	46.7	
Q1, Q3	37.7, 55.6	40.7, 55.6	
Min, Max	22.9, 70.4	28.8, 70.4	
Return Rate (%)	81%	90%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	90%	
Change in SF3602-Vitality: NBS at Week 8 from Baseline			
n	65	72	
Mean (SD)	1.6 (10.06)	4.3 (9.19)	
Median	0.0	3.0	
Q1, Q3	-3.0, 8.9	0.0, 11.9	
Min, Max	-32.7, 20.8	-17.8, 35.7	
Difference in Change from Baseline at Week 8			
n [1]	72	76	
n [2]	65	72	
MMRM: Least Squares Mean [SE] (95% CI)	0.24 [1.10] (-1.93, 2.42)	3.15 [1.04] (1.08, 5.21)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.90 [1.38] (-5.64, -0.17)		
MMRM: P-value	0.038		
Corrected Hedges' g (95% CI)	-0.326 (-0.663, 0.012)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.12		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-qre.sas V.03.05 Output file: t-chg-sf-36v2-db-gba.pdf 29AUG2023: 9:42

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in SF3602-Vitality: NBS at Week 8 from Baseline			
n	65	72	
Mean (SD)	6.9 (25.00)	14.7 (28.73)	
Median	0.0	7.0	
Q1, Q3	-7.9, 22.6	0.0, 25.6	
Min, Max	-58.8, 72.1	-30.4, 137.9	
Difference in Percent Change from Baseline at Week 8			
n [1]	72	76	
n [2]	65	72	
MMRM: Least Squares Mean [SE] (95% CI)	2.90 [3.01] (-3.05, 8.85)	10.50 [2.85] (4.85, 16.14)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-7.60 [3.75] (-15.02, -0.17)		
MMRM: P-value	0.045		
Corrected Hedges' g (95% CI)	-0.312 (-0.649, 0.026)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.22		
SF3602-Vitality: NBS at Week 12			
n	70	88	
Mean (SD)	46.7 (8.79)	47.0 (9.69)	
Median	46.7	46.7	
Q1, Q3	40.7, 52.6	40.7, 55.6	
Min, Max	28.8, 70.4	22.9, 70.4	
Return Rate (%)	81%	94%	
Number of Subjects in Risk	76	94	
Return Rate in Risk (%)	92%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in SF3602-Vitality: NBS at Week 12 from Baseline			
n	64	73	
Mean (SD)	1.0 (8.65)	3.7 (9.09)	
Median	0.0	3.0	
Q1, Q3	-4.5, 5.9	0.0, 8.9	
Min, Max	-20.8, 20.8	-17.8, 38.6	
Difference in Change from Baseline at Week 12			
n [1]	72	76	
n [2]	64	73	
MMRM: Least Squares Mean [SE] (95% CI)	0.35 [1.01] (-1.64, 2.35)		2.74 [0.95] (0.86, 4.62)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.39 [1.24] (-4.85, 0.07)		
MMRM: P-value	0.057		
Corrected Hedges' g (95% CI)	-0.293 (-0.630, 0.044)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.062		
Percent Change in SF3602-Vitality: NBS at Week 12 from Baseline			
n	64	73	
Mean (SD)	5.1 (22.26)	12.3 (27.60)	
Median	0.0	5.6	
Q1, Q3	-9.1, 10.3	0.0, 20.6	
Min, Max	-32.2, 72.1	-29.0, 149.3	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	72	76	
n [2]	64	73	
MMRM: Least Squares Mean [SE] (95% CI)	3.03 [2.86] (-2.63, 8.69)		9.02 [2.70] (3.68, 14.36)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-5.99 [3.53] (-12.96, 0.98)		
MMRM: P-value	0.092		
Corrected Hedges' g (95% CI)	-0.259 (-0.596, 0.078)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.067		
SF3602-Vitality: NBS at Week 16			
n	66	82	
Mean (SD)	47.5 (9.23)	47.2 (10.60)	
Median	46.7	46.7	
Q1, Q3	40.7, 52.6	37.7, 55.6	
Min, Max	22.9, 70.4	22.9, 70.4	
Return Rate (%)	77%	87%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	88%	90%	
Change in SF3602-Vitality: NBS at Week 16 from Baseline			
n	60	70	
Mean (SD)	1.6 (8.20)	3.4 (9.71)	
Median	1.5	3.0	
Q1, Q3	-4.5, 7.4	-3.0, 6.0	
Min, Max	-14.9, 20.8	-26.7, 35.7	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	72	76	
n [2]	60	70	
MMRM: Least Squares Mean [SE] (95% CI)	0.58 [1.12] (-1.63, 2.80)	2.56 [1.06] (0.48, 4.65)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.98 [1.41] (-4.77, 0.80)		
MMRM: P-value	0.16		
Corrected Hedges' g (95% CI)	-0.225 (-0.571, 0.121)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.23		
Percent Change in SF3602-Vitality: NBS at Week 16 from Baseline			
n	60	70	
Mean (SD)	5.9 (19.87)	11.4 (28.41)	
Median	2.7	6.0	
Q1, Q3	-10.7, 15.3	-5.6, 19.1	
Min, Max	-26.7, 51.5	-45.7, 137.9	
Difference in Percent Change from Baseline at Week 16			
n [1]	72	76	
n [2]	60	70	
MMRM: Least Squares Mean [SE] (95% CI)	3.61 [3.02] (-2.37, 9.58)	8.18 [2.85] (2.54, 13.82)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-4.57 [3.77] (-12.02, 2.87)		
MMRM: P-value	0.23		
Corrected Hedges' g (95% CI)	-0.192 (-0.538, 0.153)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.22		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
SF3602-Vitality: NBS at Week 20			
n	63	82	
Mean (SD)	47.2 (9.94)	47.3 (9.93)	
Median	46.7	46.7	
Q1, Q3	40.7, 55.6	40.7, 55.6	
Min, Max	25.9, 70.4	22.9, 70.4	
Return Rate (%)	73%	87%	
Number of Subjects in Risk	74	90	
Return Rate in Risk (%)	85%	91%	
Change in SF3602-Vitality: NBS at Week 20 from Baseline			
n	58	68	
Mean (SD)	1.5 (7.84)	3.7 (10.36)	
Median	0.0	3.0	
Q1, Q3	-3.0, 6.0	-3.0, 10.4	
Min, Max	-17.8, 17.8	-17.8, 29.7	
Difference in Change from Baseline at Week 20			
n [1]	72	76	
n [2]	58	68	
MMRM: Least Squares Mean [SE] (95% CI)	0.64 [1.09] (-1.51, 2.79)	2.70 [1.02] (0.68, 4.71)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.05 [1.36] (-4.74, 0.64)		
MMRM: P-value	0.13		
Corrected Hedges' g (95% CI)	-0.244 (-0.596, 0.107)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.19		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in SF3602-Vitality: NBS at Week 20 from Baseline			
n	58	68	
Mean (SD)	5.4 (19.59)	12.8 (29.75)	
Median	0.0	7.1	
Q1, Q3	-6.4, 15.8	-9.3, 25.8	
Min, Max	-40.8, 61.8	-29.0, 114.9	
Difference in Percent Change from Baseline at Week 20			
n [1]	72	76	
n [2]	58	68	
MMRM: Least Squares Mean [SE] (95% CI)	3.38 [2.95] (-2.44, 9.21)	9.17 [2.77] (3.70, 14.64)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-5.79 [3.65] (-13.00, 1.42)		
MMRM: P-value	0.11		
Corrected Hedges' g (95% CI)	-0.254 (-0.606, 0.098)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.20		
SF3602-Vitality: NBS at Week 24			
n	64	81	
Mean (SD)	48.4 (9.19)	47.7 (10.07)	
Median	46.7	46.7	
Q1, Q3	43.7, 55.6	40.7, 55.6	
Min, Max	22.9, 70.4	22.9, 70.4	
Return Rate (%)	74%	86%	
Number of Subjects in Risk	70	87	
Return Rate in Risk (%)	91%	93%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in SF3602-Vitality: NBS at Week 24 from Baseline			
n	58	67	
Mean (SD)	2.4 (8.50)	3.6 (10.30)	
Median	3.0	5.9	
Q1, Q3	-3.0, 5.9	-3.0, 11.9	
Min, Max	-20.8, 20.8	-17.8, 32.7	
Difference in Change from Baseline at Week 24			
n [1]	72	76	
n [2]	58	67	
MMRM: Least Squares Mean [SE] (95% CI)	1.24 [1.10] (-0.93, 3.41)	2.42 [1.03] (0.37, 4.46)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.17 [1.37] (-3.89, 1.54)		
MMRM: P-value	0.39		
Corrected Hedges' g (95% CI)	-0.139 (-0.491, 0.213)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.32		
Percent Change in SF3602-Vitality: NBS at Week 24 from Baseline			
n	58	67	
Mean (SD)	8.3 (21.89)	12.7 (29.28)	
Median	6.6	10.7	
Q1, Q3	-8.5, 13.6	-6.8, 26.0	
Min, Max	-32.2, 61.8	-31.8, 126.4	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	72	76	
n [2]	58	67	
MMRM: Least Squares Mean [SE] (95% CI)	5.23 [2.94] (-0.60, 11.05)		8.53 [2.78] (3.04, 14.02)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-3.31 [3.65] (-10.52, 3.91)		
MMRM: P-value	0.37		
Corrected Hedges' g (95% CI)	-0.145 (-0.497, 0.207)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.32		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
SF3602-Social Functioning: NBS at Baseline		
n	77	76
Mean (SD)	43.7 (10.08)	42.8 (11.18)
Median	42.3	42.3
Q1, Q3	37.3, 52.3	32.3, 52.3
Min, Max	17.2, 57.3	17.2, 57.3
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
SF3602-Social Functioning: NBS at Week 4		
n	75	89
Mean (SD)	44.8 (9.59)	45.3 (8.87)
Median	47.3	47.3
Q1, Q3	37.3, 52.3	37.3, 52.3
Min, Max	22.3, 57.3	22.3, 57.3
Return Rate (%)	87%	95%
Number of Subjects in Risk	81	94
Return Rate in Risk (%)	93%	95%
Change in SF3602-Social Functioning: NBS at Week 4 from Baseline		
n	70	74
Mean (SD)	0.5 (8.83)	2.2 (10.40)
Median	0.0	0.0
Q1, Q3	-5.0, 5.0	-5.0, 10.0
Min, Max	-20.1, 30.1	-30.1, 35.1

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	72	76	
n [2]	70	74	
MMRM: Least Squares Mean [SE] (95% CI)	0.03 [1.06] (-2.06, 2.12)		1.20 [1.01] (-0.80, 3.21)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.17 [1.32] (-3.78, 1.44)		
MMRM: P-value	0.38		
Corrected Hedges' g (95% CI)	-0.132 (-0.460, 0.195)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.46		
Percent Change in SF3602-Social Functioning: NBS at Week 4 from Baseline			
n	70	74	
Mean (SD)	3.9 (23.51)	10.9 (33.11)	
Median	0.0	0.0	
Q1, Q3	-11.8, 13.4	-8.7, 21.2	
Min, Max	-35.0, 110.3	-52.5, 157.7	
Difference in Percent Change from Baseline at Week 4			
n [1]	72	76	
n [2]	70	74	
MMRM: Least Squares Mean [SE] (95% CI)	2.05 [3.01] (-3.90, 8.00)		7.30 [2.89] (1.59, 13.02)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-5.26 [3.77] (-12.71, 2.19)		
MMRM: P-value	0.17		
Corrected Hedges' g (95% CI)	-0.209 (-0.537, 0.119)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.42		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-qre.sas V.03.05 Output file: t-chg-sf-36v2-db-gba.pdf 29AUG2023: 9:42

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
SF3602-Social Functioning: NBS at Week 8		
n	70	85
Mean (SD)	45.3 (10.04)	44.7 (9.92)
Median	47.3	47.3
Q1, Q3	37.3, 52.3	37.3, 52.3
Min, Max	17.2, 57.3	22.3, 57.3
Return Rate (%)	81%	90%
Number of Subjects in Risk	79	94
Return Rate in Risk (%)	89%	90%
Change in SF3602-Social Functioning: NBS at Week 8 from Baseline		
n	65	72
Mean (SD)	0.8 (7.76)	1.1 (10.28)
Median	0.0	0.0
Q1, Q3	-5.0, 5.0	-5.0, 10.0
Min, Max	-15.0, 15.0	-25.1, 30.1
Difference in Change from Baseline at Week 8		
n [1]	72	76
n [2]	65	72
MMRM: Least Squares Mean [SE] (95% CI)	0.10 [1.09] (-2.05, 2.25)	0.27 [1.03] (-1.76, 2.30)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.17 [1.36] (-2.85, 2.51)	
MMRM: P-value	0.90	
Corrected Hedges' g (95% CI)	-0.019 (-0.354, 0.316)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.85	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in SF3602-Social Functioning: NBS at Week 8 from Baseline			
n	65	72	
Mean (SD)	4.0 (19.62)	7.5 (30.53)	
Median	0.0	0.0	
Q1, Q3	-9.6, 13.4	-10.6, 21.9	
Min, Max	-36.8, 67.6	-47.9, 112.6	
Difference in Percent Change from Baseline at Week 8			
n [1]	72	76	
n [2]	65	72	
MMRM: Least Squares Mean [SE] (95% CI)	1.45 [3.01] (-4.50, 7.39)	4.23 [2.84] (-1.38, 9.85)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.79 [3.73] (-10.16, 4.58)		
MMRM: P-value	0.46		
Corrected Hedges' g (95% CI)	-0.115 (-0.450, 0.221)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.86		
SF3602-Social Functioning: NBS at Week 12			
n	70	88	
Mean (SD)	46.6 (8.29)	45.9 (9.73)	
Median	47.3	47.3	
Q1, Q3	42.3, 52.3	37.3, 54.8	
Min, Max	27.3, 57.3	17.2, 57.3	
Return Rate (%)	81%	94%	
Number of Subjects in Risk	76	94	
Return Rate in Risk (%)	92%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in SF3602-Social Functioning: NBS at Week 12 from Baseline			
n	64	73	
Mean (SD)	1.5 (9.44)	3.6 (11.47)	
Median	0.0	5.0	
Q1, Q3	-5.0, 10.0	0.0, 10.0	
Min, Max	-20.1, 20.1	-30.1, 35.1	
Difference in Change from Baseline at Week 12			
n [1]	72	76	
n [2]	64	73	
MMRM: Least Squares Mean [SE] (95% CI)		1.06 [1.14] (-1.19, 3.31)	2.42 [1.07] (0.30, 4.53)
MMRM: Least Squares Mean Difference [SE] (95% CI)		-1.36 [1.43] (-4.18, 1.47)	
MMRM: P-value		0.34	
Corrected Hedges' g (95% CI)		-0.148 (-0.484, 0.188)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value		0.45	
Percent Change in SF3602-Social Functioning: NBS at Week 12 from Baseline			
n	64	73	
Mean (SD)	6.7 (24.02)	14.8 (37.36)	
Median	0.0	9.6	
Q1, Q3	-10.1, 23.7	0.0, 26.9	
Min, Max	-42.4, 67.6	-63.6, 157.7	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	72	76	
n [2]	64	73	
MMRM: Least Squares Mean [SE] (95% CI)	5.33 [3.26] (-1.12, 11.77)		10.71 [3.08] (4.63, 16.79)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-5.38 [4.11] (-13.50, 2.74)		
MMRM: P-value	0.19		
Corrected Hedges' g (95% CI)	-0.204 (-0.541, 0.132)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.33		
SF3602-Social Functioning: NBS at Week 16			
n	66	82	
Mean (SD)	45.2 (9.35)	44.7 (10.75)	
Median	44.8	47.3	
Q1, Q3	42.3, 52.3	37.3, 57.3	
Min, Max	17.2, 57.3	17.2, 57.3	
Return Rate (%)	77%	87%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	88%	90%	
Change in SF3602-Social Functioning: NBS at Week 16 from Baseline			
n	60	70	
Mean (SD)	-0.1 (9.66)	1.7 (11.35)	
Median	0.0	0.0	
Q1, Q3	-5.0, 5.0	-5.0, 5.0	
Min, Max	-20.1, 25.1	-30.1, 30.1	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	72	76	
n [2]	60	70	
MMRM: Least Squares Mean [SE] (95% CI)	-0.32 [1.25] (-2.78, 2.15)		0.57 [1.17] (-1.75, 2.88)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.88 [1.59] (-4.02, 2.26)		
MMRM: P-value	0.58		
Corrected Hedges' g (95% CI)	-0.090 (-0.435, 0.255)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.25		
Percent Change in SF3602-Social Functioning: NBS at Week 16 from Baseline			
n	60	70	
Mean (SD)	2.4 (24.42)	9.0 (33.26)	
Median	0.0	0.0	
Q1, Q3	-15.5, 13.4	-9.6, 18.4	
Min, Max	-42.4, 92.0	-63.6, 112.6	
Difference in Percent Change from Baseline at Week 16			
n [1]	72	76	
n [2]	60	70	
MMRM: Least Squares Mean [SE] (95% CI)	1.51 [3.34] (-5.09, 8.11)		4.77 [3.13] (-1.41, 10.95)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-3.26 [4.21] (-11.59, 5.07)		
MMRM: P-value	0.44		
Corrected Hedges' g (95% CI)	-0.125 (-0.470, 0.221)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.22		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
SF3602-Social Functioning: NBS at Week 20		
n	63	82
Mean (SD)	46.0 (9.70)	44.7 (10.19)
Median	47.3	47.3
Q1, Q3	37.3, 57.3	37.3, 57.3
Min, Max	17.2, 57.3	17.2, 57.3
Return Rate (%)	73%	87%
Number of Subjects in Risk	74	90
Return Rate in Risk (%)	85%	91%
Change in SF3602-Social Functioning: NBS at Week 20 from Baseline		
n	58	68
Mean (SD)	1.1 (9.53)	1.6 (11.64)
Median	0.0	0.0
Q1, Q3	-5.0, 5.0	-5.0, 10.0
Min, Max	-30.1, 25.1	-25.1, 35.1
Difference in Change from Baseline at Week 20		
n [1]	72	76
n [2]	58	68
MMRM: Least Squares Mean [SE] (95% CI)	0.96 [1.22] (-1.45, 3.37)	0.46 [1.14] (-1.80, 2.72)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.50 [1.54] (-2.55, 3.56)	
MMRM: P-value	0.75	
Corrected Hedges' g (95% CI)	0.053 (-0.297, 0.404)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.84	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-qre.sas V.03.05 Output file: t-chg-sf-36v2-db-gba.pdf 29AUG2023: 9:42

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in SF3602-Social Functioning: NBS at Week 20 from Baseline			
n	58	68	
Mean (SD)	5.1 (23.56)	9.6 (36.12)	
Median	0.0	0.0	
Q1, Q3	-11.8, 21.2	-10.6, 22.5	
Min, Max	-52.5, 92.0	-53.8, 157.7	
Difference in Percent Change from Baseline at Week 20			
n [1]	72	76	
n [2]	58	68	
MMRM: Least Squares Mean [SE] (95% CI)	3.96 [3.36] (-2.68, 10.59)		5.33 [3.15] (-0.90, 11.56)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.37 [4.24] (-9.75, 7.01)		
MMRM: P-value	0.75		
Corrected Hedges' g (95% CI)	-0.053 (-0.403, 0.298)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.71		
SF3602-Social Functioning: NBS at Week 24			
n	64	81	
Mean (SD)	46.8 (8.48)	45.8 (9.50)	
Median	47.3	47.3	
Q1, Q3	42.3, 57.3	37.3, 57.3	
Min, Max	17.2, 57.3	22.3, 57.3	
Return Rate (%)	74%	86%	
Number of Subjects in Risk	70	87	
Return Rate in Risk (%)	91%	93%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in SF3602-Social Functioning: NBS at Week 24 from Baseline			
n	58	67	
Mean (SD)	2.0 (9.00)	2.2 (10.26)	
Median	0.0	0.0	
Q1, Q3	-5.0, 5.0	-5.0, 10.0	
Min, Max	-20.1, 20.1	-30.1, 30.1	
Difference in Change from Baseline at Week 24			
n [1]	72	76	
n [2]	58	67	
MMRM: Least Squares Mean [SE] (95% CI)	1.25 [1.11] (-0.95, 3.45)		1.20 [1.05] (-0.87, 3.27)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.05 [1.39] (-2.70, 2.80)		
MMRM: P-value	0.97		
Corrected Hedges' g (95% CI)	0.005 (-0.346, 0.357)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.88		
Percent Change in SF3602-Social Functioning: NBS at Week 24 from Baseline			
n	58	67	
Mean (SD)	7.5 (23.74)	10.9 (33.64)	
Median	0.0	0.0	
Q1, Q3	-8.7, 15.6	-8.7, 21.2	
Min, Max	-35.0, 73.6	-52.5, 135.2	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	72	76	
n [2]	58	67	
MMRM: Least Squares Mean [SE] (95% CI)	5.07 [3.14] (-1.15, 11.29)		7.02 [2.96] (1.18, 12.86)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.95 [3.93] (-9.71, 5.81)		
MMRM: P-value	0.62		
Corrected Hedges' g (95% CI)	-0.081 (-0.432, 0.271)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.98		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
SF3602-Role Emotional: NBS at Baseline		
n	77	76
Mean (SD)	46.1 (11.36)	44.9 (11.53)
Median	49.2	45.7
Q1, Q3	35.3, 56.2	35.3, 56.2
Min, Max	14.4, 56.2	14.4, 56.2
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
SF3602-Role Emotional: NBS at Week 4		
n	75	89
Mean (SD)	48.0 (9.75)	48.1 (9.94)
Median	49.2	52.7
Q1, Q3	42.2, 56.2	42.2, 56.2
Min, Max	17.9, 56.2	14.4, 56.2
Return Rate (%)	87%	95%
Number of Subjects in Risk	81	94
Return Rate in Risk (%)	93%	95%
Change in SF3602-Role Emotional: NBS at Week 4 from Baseline		
n	70	74
Mean (SD)	0.9 (8.01)	2.8 (11.31)
Median	0.0	0.0
Q1, Q3	-3.5, 3.5	0.0, 10.4
Min, Max	-24.4, 20.9	-27.9, 34.8

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	72	76	
n [2]	70	74	
MMRM: Least Squares Mean [SE] (95% CI)	0.64 [1.12] (-1.58, 2.86)	2.07 [1.08] (-0.06, 4.20)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.43 [1.39] (-4.17, 1.31)		
MMRM: P-value	0.30		
Corrected Hedges' g (95% CI)	-0.153 (-0.480, 0.175)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.36		
Percent Change in SF3602-Role Emotional: NBS at Week 4 from Baseline			
n	70	74	
Mean (SD)	4.5 (21.53)	12.7 (39.33)	
Median	0.0	0.0	
Q1, Q3	-7.1, 10.9	0.0, 22.9	
Min, Max	-49.5, 70.1	-65.9, 169.4	
Difference in Percent Change from Baseline at Week 4			
n [1]	72	76	
n [2]	70	74	
MMRM: Least Squares Mean [SE] (95% CI)	2.76 [3.55] (-4.25, 9.78)	9.19 [3.40] (2.47, 15.91)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-6.42 [4.35] (-15.03, 2.19)		
MMRM: P-value	0.14		
Corrected Hedges' g (95% CI)	-0.217 (-0.545, 0.111)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.37		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-qre.sas V.03.05 Output file: t-chg-sf-36v2-db-gba.pdf 29AUG2023: 9:42

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
SF3602-Role Emotional: NBS at Week 8			
n	70	85	
Mean (SD)	47.6 (9.57)	47.5 (10.27)	
Median	50.9	49.2	
Q1, Q3	42.2, 56.2	42.2, 56.2	
Min, Max	21.4, 56.2	17.9, 56.2	
Return Rate (%)	81%	90%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	90%	
Change in SF3602-Role Emotional: NBS at Week 8 from Baseline			
n	65	72	
Mean (SD)	0.2 (8.74)	2.2 (11.85)	
Median	0.0	0.0	
Q1, Q3	-3.5, 3.5	-3.5, 7.0	
Min, Max	-20.9, 24.4	-31.3, 34.8	
Difference in Change from Baseline at Week 8			
n [1]	72	76	
n [2]	65	72	
MMRM: Least Squares Mean [SE] (95% CI)	-0.27 [1.22] (-2.68, 2.13)	1.21 [1.15] (-1.06, 3.49)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.48 [1.52] (-4.49, 1.52)		
MMRM: P-value	0.33		
Corrected Hedges' g (95% CI)	-0.151 (-0.487, 0.185)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.17		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-qre.sas V.03.05 Output file: t-chg-sf-36v2-db-gba.pdf 29AUG2023: 9:42

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in SF3602-Role Emotional: NBS at Week 8 from Baseline			
n	65	72	
Mean (SD)	3.3 (23.99)	11.9 (44.19)	
Median	0.0	0.0	
Q1, Q3	-8.2, 8.2	-7.6, 18.1	
Min, Max	-39.5, 98.1	-55.8, 241.9	
Difference in Percent Change from Baseline at Week 8			
n [1]	72	76	
n [2]	65	72	
MMRM: Least Squares Mean [SE] (95% CI)	1.23 [4.05] (-6.78, 9.23)	7.48 [3.84] (-0.12, 15.08)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-6.25 [5.10] (-16.32, 3.82)		
MMRM: P-value	0.22		
Corrected Hedges' g (95% CI)	-0.190 (-0.527, 0.146)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.21		
SF3602-Role Emotional: NBS at Week 12			
n	70	88	
Mean (SD)	46.2 (10.54)	47.1 (10.72)	
Median	49.2	52.7	
Q1, Q3	38.8, 56.2	38.8, 56.2	
Min, Max	14.4, 56.2	14.4, 56.2	
Return Rate (%)	81%	94%	
Number of Subjects in Risk	76	94	
Return Rate in Risk (%)	92%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in SF3602-Role Emotional: NBS at Week 12 from Baseline			
n	64	73	
Mean (SD)	-0.4 (9.52)	1.6 (11.75)	
Median	0.0	0.0	
Q1, Q3	-5.2, 3.5	-3.5, 7.0	
Min, Max	-24.4, 24.4	-31.3, 34.8	
Difference in Change from Baseline at Week 12			
n [1]	72	76	
n [2]	64	73	
MMRM: Least Squares Mean [SE] (95% CI)	-1.01 [1.26] (-3.50, 1.48)	0.98 [1.19] (-1.37, 3.33)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.99 [1.58] (-5.12, 1.14)		
MMRM: P-value	0.21		
Corrected Hedges' g (95% CI)	-0.196 (-0.532, 0.141)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.44		
Percent Change in SF3602-Role Emotional: NBS at Week 12 from Baseline			
n	64	73	
Mean (SD)	1.9 (25.17)	10.0 (41.67)	
Median	0.0	0.0	
Q1, Q3	-10.7, 11.6	-6.2, 16.3	
Min, Max	-62.9, 98.1	-68.5, 217.7	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	72	76	
n [2]	64	73	
MMRM: Least Squares Mean [SE] (95% CI)	-0.72 [3.94] (-8.51, 7.06)		6.55 [3.72] (-0.81, 13.91)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-7.27 [4.91] (-16.98, 2.44)		
MMRM: P-value	0.14		
Corrected Hedges' g (95% CI)	-0.228 (-0.565, 0.108)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.34		
SF3602-Role Emotional: NBS at Week 16			
n	66	82	
Mean (SD)	46.0 (10.92)	46.7 (10.96)	
Median	49.2	49.2	
Q1, Q3	38.8, 56.2	35.3, 56.2	
Min, Max	14.4, 56.2	17.9, 56.2	
Return Rate (%)	77%	87%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	88%	90%	
Change in SF3602-Role Emotional: NBS at Week 16 from Baseline			
n	60	70	
Mean (SD)	-0.3 (10.21)	1.0 (10.79)	
Median	0.0	0.0	
Q1, Q3	-7.0, 3.5	-3.5, 7.0	
Min, Max	-31.3, 24.4	-31.3, 34.8	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	72	76	
n [2]	60	70	
MMRM: Least Squares Mean [SE] (95% CI)	-0.93 [1.28] (-3.46, 1.60)		0.43 [1.20] (-1.94, 2.81)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.36 [1.61] (-4.54, 1.82)		
MMRM: P-value	0.40		
Corrected Hedges' g (95% CI)	-0.136 (-0.481, 0.210)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.33		
Percent Change in SF3602-Role Emotional: NBS at Week 16 from Baseline			
n	60	70	
Mean (SD)	2.0 (27.35)	7.1 (34.05)	
Median	0.0	0.0	
Q1, Q3	-13.8, 9.9	-7.6, 14.2	
Min, Max	-55.8, 84.1	-55.8, 163.1	
Difference in Percent Change from Baseline at Week 16			
n [1]	72	76	
n [2]	60	70	
MMRM: Least Squares Mean [SE] (95% CI)	-0.78 [3.71] (-8.11, 6.55)		3.59 [3.48] (-3.29, 10.47)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-4.37 [4.55] (-13.35, 4.62)		
MMRM: P-value	0.34		
Corrected Hedges' g (95% CI)	-0.150 (-0.495, 0.195)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.29		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
SF3602-Role Emotional: NBS at Week 20			
n	63	82	
Mean (SD)	45.5 (11.44)	46.7 (10.66)	
Median	49.2	49.2	
Q1, Q3	35.3, 56.2	35.3, 56.2	
Min, Max	14.4, 56.2	14.4, 56.2	
Return Rate (%)	73%	87%	
Number of Subjects in Risk	74	90	
Return Rate in Risk (%)	85%	91%	
Change in SF3602-Role Emotional: NBS at Week 20 from Baseline			
n	58	68	
Mean (SD)	-0.6 (9.09)	1.6 (10.06)	
Median	0.0	0.0	
Q1, Q3	-3.5, 3.5	-3.5, 7.0	
Min, Max	-24.4, 24.4	-24.4, 34.8	
Difference in Change from Baseline at Week 20			
n [1]	72	76	
n [2]	58	68	
MMRM: Least Squares Mean [SE] (95% CI)	-1.53 [1.20] (-3.91, 0.86)	0.63 [1.13] (-1.61, 2.86)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.15 [1.49] (-5.11, 0.80)		
MMRM: P-value	0.15		
Corrected Hedges' g (95% CI)	-0.231 (-0.583, 0.120)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.47		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in SF3602-Role Emotional: NBS at Week 20 from Baseline			
n	58	68	
Mean (SD)	0.6 (23.60)	9.1 (38.65)	
Median	0.0	0.0	
Q1, Q3	-9.0, 6.6	-6.2, 14.2	
Min, Max	-49.5, 76.6	-59.2, 217.7	
Difference in Percent Change from Baseline at Week 20			
n [1]	72	76	
n [2]	58	68	
MMRM: Least Squares Mean [SE] (95% CI)	-2.96 [3.88] (-10.63, 4.70)	4.53 [3.65] (-2.69, 11.76)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-7.50 [4.81] (-17.01, 2.02)		
MMRM: P-value	0.12		
Corrected Hedges' g (95% CI)	-0.250 (-0.601, 0.102)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.46		
SF3602-Role Emotional: NBS at Week 24			
n	64	81	
Mean (SD)	46.8 (10.04)	46.8 (10.74)	
Median	47.5	49.2	
Q1, Q3	38.8, 56.2	38.8, 56.2	
Min, Max	17.9, 56.2	21.4, 56.2	
Return Rate (%)	74%	86%	
Number of Subjects in Risk	70	87	
Return Rate in Risk (%)	91%	93%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in SF3602-Role Emotional: NBS at Week 24 from Baseline			
n	58	67	
Mean (SD)	0.1 (7.58)	1.0 (10.50)	
Median	0.0	0.0	
Q1, Q3	-3.5, 3.5	-3.5, 7.0	
Min, Max	-17.4, 20.9	-31.3, 34.8	
Difference in Change from Baseline at Week 24			
n [1]	72	76	
n [2]	58	67	
MMRM: Least Squares Mean [SE] (95% CI)		-0.89 [1.19] (-3.24, 1.47)	0.24 [1.12] (-1.97, 2.46)
MMRM: Least Squares Mean Difference [SE] (95% CI)		-1.13 [1.47] (-4.05, 1.78)	
MMRM: P-value	0.44		
Corrected Hedges' g (95% CI)	-0.123 (-0.475, 0.228)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.55		
Percent Change in SF3602-Role Emotional: NBS at Week 24 from Baseline			
n	58	67	
Mean (SD)	2.3 (19.87)	6.9 (34.08)	
Median	0.0	0.0	
Q1, Q3	-9.0, 8.2	-6.2, 14.2	
Min, Max	-33.0, 84.1	-55.8, 163.1	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	72	76	
n [2]	58	67	
MMRM: Least Squares Mean [SE] (95% CI)	-1.32 [3.52] (-8.29, 5.64)		2.84 [3.33] (-3.74, 9.41)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-4.16 [4.27] (-12.60, 4.28)		
MMRM: P-value	0.33		
Corrected Hedges' g (95% CI)	-0.153 (-0.505, 0.199)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.48		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
SF3602-Mental Health: NBS at Baseline		
n	77	76
Mean (SD)	46.8 (10.90)	47.4 (9.80)
Median	48.3	48.3
Q1, Q3	37.8, 56.1	40.4, 56.1
Min, Max	22.1, 64.0	19.5, 64.0
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
SF3602-Mental Health: NBS at Week 4		
n	75	89
Mean (SD)	49.5 (10.43)	49.2 (9.46)
Median	50.9	50.9
Q1, Q3	40.4, 58.7	43.0, 56.1
Min, Max	22.1, 64.0	16.9, 64.0
Return Rate (%)	87%	95%
Number of Subjects in Risk	81	94
Return Rate in Risk (%)	93%	95%
Change in SF3602-Mental Health: NBS at Week 4 from Baseline		
n	70	74
Mean (SD)	2.1 (8.29)	1.7 (7.59)
Median	2.6	0.0
Q1, Q3	-2.6, 7.9	-2.6, 5.2
Min, Max	-31.4, 26.2	-15.7, 23.6

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	72	76	
n [2]	70	74	
MMRM: Least Squares Mean [SE] (95% CI)	1.96 [0.96] (0.05, 3.86)	1.86 [0.92] (0.04, 3.67)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.10 [1.21] (-2.29, 2.49)		
MMRM: P-value	0.93		
Corrected Hedges' g (95% CI)	0.012 (-0.314, 0.339)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.59		
Percent Change in SF3602-Mental Health: NBS at Week 4 from Baseline			
n	70	74	
Mean (SD)	6.7 (19.09)	5.3 (20.09)	
Median	5.1	0.0	
Q1, Q3	-4.7, 16.3	-5.2, 13.4	
Min, Max	-53.5, 74.4	-38.3, 86.2	
Difference in Percent Change from Baseline at Week 4			
n [1]	72	76	
n [2]	70	74	
MMRM: Least Squares Mean [SE] (95% CI)	6.22 [2.32] (1.63, 10.81)	5.78 [2.22] (1.39, 10.17)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.44 [2.92] (-5.33, 6.22)		
MMRM: P-value	0.88		
Corrected Hedges' g (95% CI)	0.023 (-0.304, 0.350)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.54		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
SF3602-Mental Health: NBS at Week 8		
n	70	85
Mean (SD)	49.6 (10.78)	49.2 (10.02)
Median	50.9	50.9
Q1, Q3	40.4, 58.7	43.0, 56.1
Min, Max	24.7, 64.0	19.5, 64.0
Return Rate (%)	81%	90%
Number of Subjects in Risk	79	94
Return Rate in Risk (%)	89%	90%
Change in SF3602-Mental Health: NBS at Week 8 from Baseline		
n	65	72
Mean (SD)	1.7 (8.21)	1.4 (8.28)
Median	2.6	0.0
Q1, Q3	-2.6, 7.9	-5.2, 7.8
Min, Max	-26.2, 18.3	-13.1, 23.6
Difference in Change from Baseline at Week 8		
n [1]	72	76
n [2]	65	72
MMRM: Least Squares Mean [SE] (95% CI)	1.29 [1.03] (-0.74, 3.32)	1.56 [0.97] (-0.35, 3.47)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.27 [1.29] (-2.83, 2.28)	
MMRM: P-value	0.83	
Corrected Hedges' g (95% CI)	-0.033 (-0.368, 0.302)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.66	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-qre.sas V.03.05 Output file: t-chg-sf-36v2-db-gba.pdf 29AUG2023: 9:42

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in SF3602-Mental Health: NBS at Week 8 from Baseline			
n	65	72	
Mean (SD)	5.8 (19.42)	4.6 (20.76)	
Median	4.9	0.0	
Q1, Q3	-7.4, 16.1	-9.4, 16.7	
Min, Max	-44.6, 67.1	-32.4, 67.0	
Difference in Percent Change from Baseline at Week 8			
n [1]	72	76	
n [2]	65	72	
MMRM: Least Squares Mean [SE] (95% CI)	4.76 [2.44] (-0.07, 9.59)	4.98 [2.30] (0.44, 9.53)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.23 [3.08] (-6.31, 5.86)		
MMRM: P-value	0.94		
Corrected Hedges' g (95% CI)	-0.012 (-0.347, 0.324)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.71		
SF3602-Mental Health: NBS at Week 12			
n	70	88	
Mean (SD)	49.0 (9.44)	48.5 (10.40)	
Median	50.9	50.9	
Q1, Q3	43.0, 56.1	39.1, 56.1	
Min, Max	27.3, 64.0	16.9, 64.0	
Return Rate (%)	81%	94%	
Number of Subjects in Risk	76	94	
Return Rate in Risk (%)	92%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in SF3602-Mental Health: NBS at Week 12 from Baseline			
n	64	73	
Mean (SD)	1.8 (8.39)	1.1 (7.47)	
Median	2.6	0.0	
Q1, Q3	-2.6, 7.9	-2.6, 5.2	
Min, Max	-23.6, 23.5	-18.3, 20.9	
Difference in Change from Baseline at Week 12			
n [1]	72	76	
n [2]	64	73	
MMRM: Least Squares Mean [SE] (95% CI)		1.57 [0.98] (-0.36, 3.50)	1.32 [0.91] (-0.48, 3.11)
MMRM: Least Squares Mean Difference [SE] (95% CI)		0.25 [1.21] (-2.14, 2.65)	
MMRM: P-value	0.83		
Corrected Hedges' g (95% CI)	0.033 (-0.303, 0.368)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.56		
Percent Change in SF3602-Mental Health: NBS at Week 12 from Baseline			
n	64	73	
Mean (SD)	7.2 (21.82)	3.4 (18.33)	
Median	4.7	0.0	
Q1, Q3	-5.6, 18.4	-6.5, 11.5	
Min, Max	-40.1, 62.3	-42.6, 55.4	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	72	76	
n [2]	64	73	
MMRM: Least Squares Mean [SE] (95% CI)		6.40 [2.37] (1.73, 11.08)	3.98 [2.20] (-0.38, 8.33)
MMRM: Least Squares Mean Difference [SE] (95% CI)		2.43 [2.94] (-3.40, 8.25)	
MMRM: P-value		0.41	
Corrected Hedges' g (95% CI)		0.128 (-0.208, 0.464)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value		0.43	
SF3602-Mental Health: NBS at Week 16			
n	66	82	
Mean (SD)	48.7 (10.61)	49.0 (10.89)	
Median	48.3	52.2	
Q1, Q3	40.4, 58.7	43.0, 56.1	
Min, Max	14.2, 64.0	19.5, 64.0	
Return Rate (%)	77%	87%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	88%	90%	
Change in SF3602-Mental Health: NBS at Week 16 from Baseline			
n	60	70	
Mean (SD)	1.5 (7.48)	1.4 (8.46)	
Median	2.6	1.3	
Q1, Q3	-5.2, 5.2	-2.6, 5.2	
Min, Max	-13.1, 20.9	-18.3, 26.2	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	72	76	
n [2]	60	70	
MMRM: Least Squares Mean [SE] (95% CI)	1.09 [1.03] (-0.95, 3.14)	1.68 [0.96] (-0.22, 3.59)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.59 [1.30] (-3.16, 1.97)		
MMRM: P-value	0.65		
Corrected Hedges' g (95% CI)	-0.073 (-0.418, 0.272)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.76		
Percent Change in SF3602-Mental Health: NBS at Week 16 from Baseline			
n	60	70	
Mean (SD)	5.1 (19.49)	4.4 (20.93)	
Median	4.4	2.1	
Q1, Q3	-9.6, 14.4	-6.5, 14.0	
Min, Max	-35.5, 76.6	-38.8, 74.4	
Difference in Percent Change from Baseline at Week 16			
n [1]	72	76	
n [2]	60	70	
MMRM: Least Squares Mean [SE] (95% CI)	4.04 [2.55] (-1.00, 9.08)	4.96 [2.37] (0.27, 9.65)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.92 [3.21] (-7.28, 5.43)		
MMRM: P-value	0.77		
Corrected Hedges' g (95% CI)	-0.046 (-0.391, 0.299)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.76		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
SF3602-Mental Health: NBS at Week 20		
n	63	82
Mean (SD)	48.5 (10.88)	48.8 (10.39)
Median	50.9	50.9
Q1, Q3	40.4, 56.1	40.4, 56.1
Min, Max	22.1, 64.0	16.9, 64.0
Return Rate (%)	73%	87%
Number of Subjects in Risk	74	90
Return Rate in Risk (%)	85%	91%
Change in SF3602-Mental Health: NBS at Week 20 from Baseline		
n	58	68
Mean (SD)	1.5 (9.70)	1.6 (7.66)
Median	2.6	1.3
Q1, Q3	-2.6, 5.2	-2.6, 5.2
Min, Max	-26.2, 26.2	-15.7, 28.8
Difference in Change from Baseline at Week 20		
n [1]	72	76
n [2]	58	68
MMRM: Least Squares Mean [SE] (95% CI)	1.14 [1.08] (-0.99, 3.27)	1.83 [1.01] (-0.16, 3.82)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.69 [1.36] (-3.38, 2.01)	
MMRM: P-value	0.62	
Corrected Hedges' g (95% CI)	-0.083 (-0.433, 0.268)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.93	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in SF3602-Mental Health: NBS at Week 20 from Baseline			
n	58	68	
Mean (SD)	6.1 (23.98)	4.8 (19.26)	
Median	5.4	2.1	
Q1, Q3	-8.0, 16.3	-4.6, 11.1	
Min, Max	-51.6, 74.4	-38.3, 81.8	
Difference in Percent Change from Baseline at Week 20			
n [1]	72	76	
n [2]	58	68	
MMRM: Least Squares Mean [SE] (95% CI)	5.23 [2.61] (0.07, 10.40)		5.34 [2.43] (0.53, 10.15)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.11 [3.31] (-6.66, 6.44)		
MMRM: P-value	0.97		
Corrected Hedges' g (95% CI)	-0.005 (-0.356, 0.345)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.97		
SF3602-Mental Health: NBS at Week 24			
n	64	81	
Mean (SD)	49.6 (10.02)	49.1 (9.52)	
Median	50.9	50.9	
Q1, Q3	43.0, 58.7	43.0, 56.1	
Min, Max	22.1, 64.0	22.1, 64.0	
Return Rate (%)	74%	86%	
Number of Subjects in Risk	70	87	
Return Rate in Risk (%)	91%	93%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in SF3602-Mental Health: NBS at Week 24 from Baseline			
n	58	67	
Mean (SD)	2.4 (8.63)	1.2 (7.67)	
Median	2.6	0.0	
Q1, Q3	-2.6, 7.9	-2.6, 5.2	
Min, Max	-20.9, 23.5	-20.9, 18.3	
Difference in Change from Baseline at Week 24			
n [1]	72	76	
n [2]	58	67	
MMRM: Least Squares Mean [SE] (95% CI)	1.54 [1.02] (-0.46, 3.55)	1.30 [0.95] (-0.57, 3.18)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.24 [1.27] (-2.28, 2.75)		
MMRM: P-value	0.85		
Corrected Hedges' g (95% CI)	0.030 (-0.321, 0.382)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.60		
Percent Change in SF3602-Mental Health: NBS at Week 24 from Baseline			
n	58	67	
Mean (SD)	8.2 (22.02)	4.1 (18.09)	
Median	4.3	0.0	
Q1, Q3	-5.4, 19.2	-5.7, 13.4	
Min, Max	-34.1, 78.6	-37.3, 48.5	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	72	76	
n [2]	58	67	
MMRM: Least Squares Mean [SE] (95% CI)	6.02 [2.40] (1.28, 10.75)		4.53 [2.24] (0.09, 8.96)
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.49 [3.00] (-4.43, 7.41)		
MMRM: P-value	0.62		
Corrected Hedges' g (95% CI)	0.081 (-0.271, 0.433)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.60		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
SF3602-Physical Component Summary at Baseline		
n	77	76
Mean (SD)	39.0 (8.84)	38.8 (10.21)
Median	38.5	38.0
Q1, Q3	33.0, 45.4	29.7, 47.5
Min, Max	18.0, 59.1	16.8, 58.8
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
SF3602-Physical Component Summary at Week 4		
n	75	89
Mean (SD)	41.6 (8.69)	41.2 (9.51)
Median	42.7	41.1
Q1, Q3	36.1, 47.8	34.3, 48.6
Min, Max	19.2, 59.1	19.0, 62.2
Return Rate (%)	87%	95%
Number of Subjects in Risk	81	94
Return Rate in Risk (%)	93%	95%
Change in SF3602-Physical Component Summary at Week 4 from Baseline		
n	70	74
Mean (SD)	2.2 (6.37)	2.4 (5.90)
Median	2.1	2.1
Q1, Q3	-2.0, 6.6	-1.3, 6.5
Min, Max	-10.7, 16.5	-13.9, 15.5

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	72	76	
n [2]	70	74	
MMRM: Least Squares Mean [SE] (95% CI)	2.04 [0.78] (0.49, 3.59)		2.13 [0.75] (0.64, 3.61)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.09 [0.97] (-2.00, 1.82)		
MMRM: P-value	0.93		
Corrected Hedges' g (95% CI)	-0.014 (-0.340, 0.313)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.59		
Percent Change in SF3602-Physical Component Summary at Week 4 from Baseline			
n	70	74	
Mean (SD)	7.2 (17.61)	8.5 (18.92)	
Median	5.3	5.0	
Q1, Q3	-5.9, 18.4	-2.9, 19.8	
Min, Max	-25.8, 56.6	-40.9, 50.9	
Difference in Percent Change from Baseline at Week 4			
n [1]	72	76	
n [2]	70	74	
MMRM: Least Squares Mean [SE] (95% CI)	7.42 [2.25] (2.97, 11.87)		8.23 [2.16] (3.96, 12.49)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.81 [2.76] (-6.27, 4.65)		
MMRM: P-value	0.77		
Corrected Hedges' g (95% CI)	-0.043 (-0.370, 0.284)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.34		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
SF3602-Physical Component Summary at Week 8			
n	70	85	
Mean (SD)	41.2 (7.72)	41.5 (9.01)	
Median	41.8	42.5	
Q1, Q3	36.5, 47.3	34.2, 48.3	
Min, Max	22.4, 56.9	18.6, 58.8	
Return Rate (%)	81%	90%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	90%	
Change in SF3602-Physical Component Summary at Week 8 from Baseline			
n	65	72	
Mean (SD)	2.0 (7.06)	2.5 (6.12)	
Median	2.9	1.8	
Q1, Q3	-2.2, 6.8	-1.6, 4.6	
Min, Max	-17.1, 14.8	-10.3, 26.1	
Difference in Change from Baseline at Week 8			
n [1]	72	76	
n [2]	65	72	
MMRM: Least Squares Mean [SE] (95% CI)	1.71 [0.80] (0.14, 3.28)	2.32 [0.75] (0.83, 3.80)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.61 [0.97] (-2.53, 1.32)		
MMRM: P-value	0.53		
Corrected Hedges' g (95% CI)	-0.094 (-0.430, 0.241)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.95		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in SF3602-Physical Component Summary at Week 8 from Baseline			
n	65	72	
Mean (SD)	7.9 (19.24)	9.2 (20.67)	
Median	7.3	3.9	
Q1, Q3	-4.8, 18.8	-3.1, 14.4	
Min, Max	-29.0, 52.5	-26.8, 105.7	
Difference in Percent Change from Baseline at Week 8			
n [1]	72	76	
n [2]	65	72	
MMRM: Least Squares Mean [SE] (95% CI)	7.71 [2.31] (3.13, 12.28)		9.00 [2.18] (4.68, 13.32)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.29 [2.83] (-6.88, 4.29)		
MMRM: P-value	0.65		
Corrected Hedges' g (95% CI)	-0.069 (-0.405, 0.266)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.98		
SF3602-Physical Component Summary at Week 12			
n	70	88	
Mean (SD)	41.9 (7.76)	41.4 (9.08)	
Median	42.0	43.6	
Q1, Q3	36.7, 48.0	34.3, 47.6	
Min, Max	25.7, 56.5	21.8, 58.4	
Return Rate (%)	81%	94%	
Number of Subjects in Risk	76	94	
Return Rate in Risk (%)	92%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in SF3602-Physical Component Summary at Week 12 from Baseline			
n	64	73	
Mean (SD)	2.0 (7.43)	2.9 (6.40)	
Median	2.4	2.7	
Q1, Q3	-2.0, 7.1	-1.6, 7.2	
Min, Max	-17.3, 17.5	-9.4, 27.5	
Difference in Change from Baseline at Week 12			
n [1]	72	76	
n [2]	64	73	
MMRM: Least Squares Mean [SE] (95% CI)	1.96 [0.82] (0.34, 3.58)	2.61 [0.77] (1.09, 4.14)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.66 [1.01] (-2.66, 1.34)		
MMRM: P-value	0.52		
Corrected Hedges' g (95% CI)	-0.099 (-0.435, 0.236)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.51		
Percent Change in SF3602-Physical Component Summary at Week 12 from Baseline			
n	64	73	
Mean (SD)	7.2 (19.58)	10.6 (21.75)	
Median	6.0	6.2	
Q1, Q3	-5.7, 19.9	-3.1, 17.1	
Min, Max	-37.9, 57.1	-21.5, 111.1	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	72	76	
n [2]	64	73	
MMRM: Least Squares Mean [SE] (95% CI)	8.01 [2.38] (3.31, 12.71)		10.25 [2.24] (5.83, 14.68)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.25 [2.92] (-8.03, 3.54)		
MMRM: P-value	0.44		
Corrected Hedges' g (95% CI)	-0.117 (-0.453, 0.219)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.31		
SF3602-Physical Component Summary at Week 16			
n	66	82	
Mean (SD)	42.6 (8.65)	41.9 (9.67)	
Median	41.7	42.5	
Q1, Q3	37.0, 50.3	34.4, 51.0	
Min, Max	23.2, 60.1	18.8, 61.6	
Return Rate (%)	77%	87%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	88%	90%	
Change in SF3602-Physical Component Summary at Week 16 from Baseline			
n	60	70	
Mean (SD)	2.8 (7.81)	2.8 (7.67)	
Median	3.1	2.2	
Q1, Q3	-3.2, 7.9	-2.2, 7.1	
Min, Max	-14.6, 18.3	-15.7, 24.8	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	72	76	
n [2]	60	70	
MMRM: Least Squares Mean [SE] (95% CI)	2.32 [0.96] (0.42, 4.22)	2.51 [0.90] (0.72, 4.30)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.20 [1.22] (-2.61, 2.22)		
MMRM: P-value	0.87		
Corrected Hedges' g (95% CI)	-0.026 (-0.371, 0.319)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.95		
Percent Change in SF3602-Physical Component Summary at Week 16 from Baseline			
n	60	70	
Mean (SD)	9.3 (22.37)	10.2 (25.14)	
Median	7.6	5.8	
Q1, Q3	-7.3, 21.3	-4.8, 19.7	
Min, Max	-32.1, 62.8	-44.2, 100.2	
Difference in Percent Change from Baseline at Week 16			
n [1]	72	76	
n [2]	60	70	
MMRM: Least Squares Mean [SE] (95% CI)	9.25 [2.81] (3.70, 14.80)	9.62 [2.64] (4.40, 14.84)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.38 [3.57] (-7.43, 6.68)		
MMRM: P-value	0.92		
Corrected Hedges' g (95% CI)	-0.017 (-0.362, 0.328)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.71		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
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Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
SF3602-Physical Component Summary at Week 20		
n	63	82
Mean (SD)	42.0 (8.58)	42.1 (9.51)
Median	42.3	43.0
Q1, Q3	35.3, 46.0	35.0, 49.8
Min, Max	24.1, 59.9	17.2, 58.6
Return Rate (%)	73%	87%
Number of Subjects in Risk	74	90
Return Rate in Risk (%)	85%	91%
Change in SF3602-Physical Component Summary at Week 20 from Baseline		
n	58	68
Mean (SD)	2.7 (6.52)	2.9 (7.68)
Median	2.8	2.8
Q1, Q3	-1.4, 6.9	-1.3, 6.9
Min, Max	-13.3, 20.3	-16.5, 24.8
Difference in Change from Baseline at Week 20		
n [1]	72	76
n [2]	58	68
MMRM: Least Squares Mean [SE] (95% CI)	1.98 [0.91] (0.18, 3.78)	2.61 [0.86] (0.92, 4.30)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.63 [1.15] (-2.89, 1.64)	
MMRM: P-value	0.58	
Corrected Hedges' g (95% CI)	-0.089 (-0.440, 0.261)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.94	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019
Source: t-chg-qre.sas V.03.05 Output file: t-chg-sf-36v2-db-gba.pdf 29AUG2023: 9:42

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in SF3602-Physical Component Summary at Week 20 from Baseline			
n	58	68	
Mean (SD)	8.2 (17.65)	10.3 (25.83)	
Median	5.7	5.9	
Q1, Q3	-3.5, 18.6	-2.7, 20.0	
Min, Max	-29.3, 71.9	-48.9, 100.5	
Difference in Percent Change from Baseline at Week 20			
n [1]	72	76	
n [2]	58	68	
MMRM: Least Squares Mean [SE] (95% CI)	7.70 [2.70] (2.35, 13.04)		10.08 [2.54] (5.05, 15.10)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.38 [3.41] (-9.13, 4.37)		
MMRM: P-value	0.49		
Corrected Hedges' g (95% CI)	-0.114 (-0.464, 0.237)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.85		
SF3602-Physical Component Summary at Week 24			
n	64	81	
Mean (SD)	43.0 (7.60)	42.5 (9.23)	
Median	43.1	42.9	
Q1, Q3	39.0, 47.2	36.2, 50.8	
Min, Max	21.0, 58.2	23.0, 57.6	
Return Rate (%)	74%	86%	
Number of Subjects in Risk	70	87	
Return Rate in Risk (%)	91%	93%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in SF3602-Physical Component Summary at Week 24 from Baseline			
n	58	67	
Mean (SD)	3.2 (7.02)	2.4 (7.20)	
Median	2.4	2.5	
Q1, Q3	-1.0, 8.3	-0.3, 6.0	
Min, Max	-16.2, 21.8	-15.0, 26.8	
Difference in Change from Baseline at Week 24			
n [1]	72	76	
n [2]	58	67	
MMRM: Least Squares Mean [SE] (95% CI)	2.81 [0.88] (1.07, 4.54)	2.10 [0.83] (0.46, 3.73)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.71 [1.10] (-1.46, 2.88)		
MMRM: P-value	0.52		
Corrected Hedges' g (95% CI)	0.105 (-0.247, 0.457)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.55		
Percent Change in SF3602-Physical Component Summary at Week 24 from Baseline			
n	58	67	
Mean (SD)	10.5 (20.82)	9.0 (23.98)	
Median	5.3	6.3	
Q1, Q3	-3.5, 22.3	-0.5, 15.0	
Min, Max	-31.1, 77.2	-36.3, 108.4	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	72	76	
n [2]	58	67	
MMRM: Least Squares Mean [SE] (95% CI)	10.43 [2.67] (5.16, 15.71)		8.50 [2.51] (3.54, 13.47)
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.93 [3.36] (-4.72, 8.58)		
MMRM: P-value	0.57		
Corrected Hedges' g (95% CI)	0.094 (-0.258, 0.446)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.65		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)
SF3602-Mental Component Summary at Baseline		
n	77	76
Mean (SD)	48.1 (10.45)	47.6 (9.51)
Median	49.9	49.8
Q1, Q3	40.5, 56.5	39.2, 55.4
Min, Max	22.9, 65.0	26.4, 63.1
Return Rate (%)	90%	81%
Number of Subjects in Risk	86	94
Return Rate in Risk (%)	90%	81%
SF3602-Mental Component Summary at Week 4		
n	75	89
Mean (SD)	50.1 (9.87)	50.3 (9.12)
Median	51.5	51.7
Q1, Q3	43.5, 58.0	45.8, 57.2
Min, Max	22.3, 68.0	20.1, 64.9
Return Rate (%)	87%	95%
Number of Subjects in Risk	81	94
Return Rate in Risk (%)	93%	95%
Change in SF3602-Mental Component Summary at Week 4 from Baseline		
n	70	74
Mean (SD)	1.2 (7.75)	2.3 (9.02)
Median	1.4	0.9
Q1, Q3	-3.9, 5.5	-3.7, 7.8
Min, Max	-18.8, 18.1	-16.9, 25.2

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 4			
n [1]	72	76	
n [2]	70	74	
MMRM: Least Squares Mean [SE] (95% CI)	0.89 [1.02] (-1.14, 2.91)	2.00 [0.98] (0.06, 3.94)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.11 [1.27] (-3.62, 1.39)		
MMRM: P-value	0.38		
Corrected Hedges' g (95% CI)	-0.130 (-0.458, 0.197)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.32		
Percent Change in SF3602-Mental Component Summary at Week 4 from Baseline			
n	70	74	
Mean (SD)	4.1 (17.42)	7.3 (23.61)	
Median	2.8	2.0	
Q1, Q3	-8.0, 11.3	-5.9, 15.8	
Min, Max	-33.5, 45.2	-37.4, 79.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	72	76	
n [2]	70	74	
MMRM: Least Squares Mean [SE] (95% CI)	3.20 [2.49] (-1.72, 8.12)	6.28 [2.38] (1.58, 10.98)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-3.08 [3.07] (-9.16, 3.00)		
MMRM: P-value	0.32		
Corrected Hedges' g (95% CI)	-0.148 (-0.476, 0.179)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.42		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
SF3602-Mental Component Summary at Week 8			
n	70	85	
Mean (SD)	50.1 (9.53)	49.9 (9.68)	
Median	50.9	51.1	
Q1, Q3	44.1, 58.4	44.2, 57.8	
Min, Max	25.9, 63.9	16.4, 64.4	
Return Rate (%)	81%	90%	
Number of Subjects in Risk	79	94	
Return Rate in Risk (%)	89%	90%	
Change in SF3602-Mental Component Summary at Week 8 from Baseline			
n	65	72	
Mean (SD)	0.8 (7.81)	1.8 (9.34)	
Median	0.8	-0.5	
Q1, Q3	-4.9, 6.4	-4.1, 7.6	
Min, Max	-15.9, 18.1	-14.2, 26.5	
Difference in Change from Baseline at Week 8			
n [1]	72	76	
n [2]	65	72	
MMRM: Least Squares Mean [SE] (95% CI)	0.19 [1.07] (-1.92, 2.31)	1.29 [1.01] (-0.71, 3.29)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.10 [1.33] (-3.72, 1.53)		
MMRM: P-value	0.41		
Corrected Hedges' g (95% CI)	-0.127 (-0.462, 0.209)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.68		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in SF3602-Mental Component Summary at Week 8 from Baseline			
n	65	72	
Mean (SD)	3.7 (18.46)	5.9 (23.88)	
Median	1.4	-0.9	
Q1, Q3	-9.8, 13.1	-8.0, 18.0	
Min, Max	-28.4, 55.5	-42.5, 84.2	
Difference in Percent Change from Baseline at Week 8			
n [1]	72	76	
n [2]	65	72	
MMRM: Least Squares Mean [SE] (95% CI)	2.10 [2.62] (-3.08, 7.29)	4.50 [2.48] (-0.40, 9.39)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.40 [3.26] (-8.83, 4.04)		
MMRM: P-value	0.46		
Corrected Hedges' g (95% CI)	-0.113 (-0.449, 0.223)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.71		
SF3602-Mental Component Summary at Week 12			
n	70	88	
Mean (SD)	49.4 (9.66)	49.6 (10.26)	
Median	50.5	52.3	
Q1, Q3	43.1, 57.5	41.8, 57.3	
Min, Max	23.8, 63.6	19.0, 65.2	
Return Rate (%)	81%	94%	
Number of Subjects in Risk	76	94	
Return Rate in Risk (%)	92%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in SF3602-Mental Component Summary at Week 12 from Baseline			
n	64	73	
Mean (SD)	0.5 (8.28)	1.8 (10.16)	
Median	0.0	0.8	
Q1, Q3	-4.4, 5.8	-3.6, 6.6	
Min, Max	-19.7, 22.1	-29.8, 27.2	
Difference in Change from Baseline at Week 12			
n [1]	72	76	
n [2]	64	73	
MMRM: Least Squares Mean [SE] (95% CI)	-0.01 [1.13] (-2.25, 2.22)	1.49 [1.06] (-0.61, 3.59)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.50 [1.41] (-4.30, 1.29)		
MMRM: P-value	0.29		
Corrected Hedges' g (95% CI)	-0.165 (-0.501, 0.171)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.40		
Percent Change in SF3602-Mental Component Summary at Week 12 from Baseline			
n	64	73	
Mean (SD)	3.2 (20.05)	6.0 (24.96)	
Median	-0.1	1.5	
Q1, Q3	-8.3, 13.8	-7.1, 16.0	
Min, Max	-34.8, 60.5	-57.3, 86.7	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 12			
n [1]	72	76	
n [2]	64	73	
MMRM: Least Squares Mean [SE] (95% CI)	1.83 [2.71] (-3.53, 7.19)		4.99 [2.55] (-0.04, 10.02)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-3.16 [3.38] (-9.84, 3.52)		
MMRM: P-value	0.35		
Corrected Hedges' g (95% CI)	-0.145 (-0.481, 0.191)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.51		
SF3602-Mental Component Summary at Week 16			
n	66	82	
Mean (SD)	48.8 (10.03)	49.1 (10.88)	
Median	49.7	51.4	
Q1, Q3	41.6, 56.8	43.2, 57.9	
Min, Max	14.4, 65.7	19.1, 65.1	
Return Rate (%)	77%	87%	
Number of Subjects in Risk	75	91	
Return Rate in Risk (%)	88%	90%	
Change in SF3602-Mental Component Summary at Week 16 from Baseline			
n	60	70	
Mean (SD)	-0.1 (7.62)	1.2 (9.61)	
Median	0.2	0.0	
Q1, Q3	-5.9, 4.4	-5.3, 6.9	
Min, Max	-17.9, 19.3	-18.9, 24.9	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Change from Baseline at Week 16			
n [1]	72	76	
n [2]	60	70	
MMRM: Least Squares Mean [SE] (95% CI)	-0.58 [1.13] (-2.80, 1.65)		0.89 [1.06] (-1.20, 2.98)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.47 [1.41] (-4.24, 1.31)		
MMRM: P-value	0.30		
Corrected Hedges' g (95% CI)	-0.166 (-0.511, 0.180)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.55		
Percent Change in SF3602-Mental Component Summary at Week 16 from Baseline			
n	60	70	
Mean (SD)	1.2 (18.29)	4.0 (23.71)	
Median	0.4	0.0	
Q1, Q3	-12.0, 9.8	-9.6, 15.6	
Min, Max	-36.8, 48.2	-35.4, 72.8	
Difference in Percent Change from Baseline at Week 16			
n [1]	72	76	
n [2]	60	70	
MMRM: Least Squares Mean [SE] (95% CI)	0.13 [2.75] (-5.31, 5.57)		3.12 [2.58] (-1.98, 8.21)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.99 [3.44] (-9.78, 3.80)		
MMRM: P-value	0.39		
Corrected Hedges' g (95% CI)	-0.139 (-0.484, 0.207)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.51		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
SF3602-Mental Component Summary at Week 20			
n	63	82	
Mean (SD)	49.0 (11.02)	49.0 (10.36)	
Median	50.2	52.2	
Q1, Q3	40.9, 58.4	41.9, 56.6	
Min, Max	23.1, 65.7	14.5, 69.2	
Return Rate (%)	73%	87%	
Number of Subjects in Risk	74	90	
Return Rate in Risk (%)	85%	91%	
Change in SF3602-Mental Component Summary at Week 20 from Baseline			
n	58	68	
Mean (SD)	0.2 (8.78)	1.4 (9.52)	
Median	0.0	1.2	
Q1, Q3	-4.8, 5.3	-4.5, 7.3	
Min, Max	-24.7, 19.4	-20.1, 29.5	
Difference in Change from Baseline at Week 20			
n [1]	72	76	
n [2]	58	68	
MMRM: Least Squares Mean [SE] (95% CI)	-0.25 [1.16] (-2.55, 2.04)	0.90 [1.09] (-1.25, 3.06)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.16 [1.46] (-4.04, 1.72)		
MMRM: P-value	0.43		
Corrected Hedges' g (95% CI)	-0.129 (-0.480, 0.222)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.43		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Percent Change in SF3602-Mental Component Summary at Week 20 from Baseline			
n	58	68	
Mean (SD)	2.1 (20.36)	5.0 (23.77)	
Median	0.2	2.5	
Q1, Q3	-9.5, 12.1	-7.7, 15.1	
Min, Max	-49.8, 58.8	-49.4, 80.0	
Difference in Percent Change from Baseline at Week 20			
n [1]	72	76	
n [2]	58	68	
MMRM: Least Squares Mean [SE] (95% CI)	0.76 [2.80] (-4.76, 6.29)	3.53 [2.62] (-1.65, 8.71)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.77 [3.50] (-9.69, 4.16)		
MMRM: P-value	0.43		
Corrected Hedges' g (95% CI)	-0.128 (-0.479, 0.223)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.44		
SF3602-Mental Component Summary at Week 24			
n	64	81	
Mean (SD)	50.0 (9.92)	49.5 (9.42)	
Median	50.9	52.1	
Q1, Q3	43.5, 57.7	43.9, 56.0	
Min, Max	20.2, 67.0	21.4, 64.6	
Return Rate (%)	74%	86%	
Number of Subjects in Risk	70	87	
Return Rate in Risk (%)	91%	93%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Change in SF3602-Mental Component Summary at Week 24 from Baseline			
n	58	67	
Mean (SD)	1.1 (7.48)	1.4 (8.96)	
Median	1.2	-0.4	
Q1, Q3	-4.2, 6.0	-4.1, 7.7	
Min, Max	-21.4, 17.8	-17.9, 24.6	
Difference in Change from Baseline at Week 24			
n [1]	72	76	
n [2]	58	67	
MMRM: Least Squares Mean [SE] (95% CI)	0.08 [1.06] (-2.01, 2.17)	0.94 [0.99] (-1.02, 2.91)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.86 [1.30] (-3.44, 1.71)		
MMRM: P-value	0.51		
Corrected Hedges' g (95% CI)	-0.106 (-0.458, 0.246)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.93		
Percent Change in SF3602-Mental Component Summary at Week 24 from Baseline			
n	58	67	
Mean (SD)	3.9 (16.94)	5.2 (22.47)	
Median	2.3	-0.8	
Q1, Q3	-8.1, 12.6	-7.1, 16.1	
Min, Max	-35.2, 54.7	-38.8, 78.2	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

Table 2.7001: Analysis of SF-36v2, Change and % Change from Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	MMB (N=86)	RUX (N=94)	
Difference in Percent Change from Baseline at Week 24			
n [1]	72	76	
n [2]	58	67	
MMRM: Least Squares Mean [SE] (95% CI)	1.55 [2.52] (-3.42, 6.53)		3.72 [2.37] (-0.96, 8.40)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.16 [3.09] (-8.26, 3.93)		
MMRM: P-value	0.48		
Corrected Hedges' g (95% CI)	-0.112 (-0.463, 0.240)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.77		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline platelet count (<100, 100-200, >200 10^9/L), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 01JUL2019

1.10 Sicherheit

1.10.1 Zusammenfassung

GSK Oncology
Study GS-US-352-0101

Table 3.0111: TEAEs: Overall Summary
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Open Label Phase (Week 24 Onward)			Overall Exposed to MMB
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Subjects With Any				
TEAE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
TEAE with Grade >=3	46 (71.9%)	53 (63.1%)	99 (66.9%)	120 (70.6%)
TEAE with Grade 3 or 4	43 (67.2%)	52 (61.9%)	95 (64.2%)	116 (68.2%)
TEAE Related to Study Drug	42 (65.6%)	58 (69.0%)	100 (67.6%)	129 (75.9%)
TEAE Related to Study Drug with Grade >=3	20 (31.3%)	26 (31.0%)	46 (31.1%)	64 (37.6%)
Serious TEAE	35 (54.7%)	38 (45.2%)	73 (49.3%)	87 (51.2%)
Serious TEAE Related to Study Drug	14 (21.9%)	8 (9.5%)	22 (14.9%)	29 (17.1%)
Non-Fatal SAEs	31 (48.4%)	35 (41.7%)	66 (44.6%)	80 (47.1%)
TEAE Leading to Premature Discontinuation of Study Drug	21 (32.8%)	22 (26.2%)	43 (29.1%)	61 (35.9%)
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug	15 (23.4%)	26 (31.0%)	41 (27.7%)	57 (33.5%)
TEAE Leading to Death	9 (14.1%)	9 (10.7%)	18 (12.2%)	22 (12.9%)
TEAE of Interest				
Peripheral Neuropathy SMQ (Narrow Term Only)	10 (15.6%)	14 (16.7%)	24 (16.2%)	32 (18.8%)
Peripheral Neuropathy SMQ (Narrow Term Only) -> Study Drug Disc	3 (4.7%)	3 (3.6%)	6 (4.1%)	6 (3.5%)
Non-Hematological	58 (90.6%)	81 (96.4%)	139 (93.9%)	163 (95.9%)
Cataract	6 (9.4%)	3 (3.6%)	9 (6.1%)	11 (6.5%)
First Dose Effect	-	1 (1.2%)	-	6 (3.5%)
Serious TEAEs for First Dose Effect	-	0	-	1 (0.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Severity grades were defined by The CTCAE Version 4.03
Related to study drug under OL phase is defined as related to OL MMB.
TEAE = Treatment-Emergent Adverse Event

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-ol.sas V.03.05 Output file: t-aebrief-ol.pdf 29AUG2023: 9:41

Table 3.1801: TEAEs with Grade 2 or less
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=86)	RUX (N=94)	Total (N=180)	(MMB->MMB) (N=64)	(RUX->MMB) (N=84)	Total (N=148)
Number of subjects, n(%)	77 (89.5%)	90 (95.7%)	167 (92.8%)	58 (90.6%)	81 (96.4%)	139 (93.9%)
Unadjusted Relative Risk (95% CI)	0.94 (0.86, 1.02)					
p-value [1]	0.12					
Unadjusted Odds Ratio (95% CI)	0.38 (0.11, 1.28)					
p-value [1]	0.12					
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.14, 0.01)					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-gle2-gba.sas V.03.05 Output file: t-aesum-gle2-gba.pdf 24AUG2023:12:49

1.10.2 UE

Table 3.0211: TEAEs by SOC and PT
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	OL Phase (Week 24 Onward)			Overall Exposed to MMB
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Gastrointestinal disorders	30 (46.9%)	54 (64.3%)	84 (56.8%)	112 (65.9%)
Diarrhoea	14 (21.9%)	21 (25.0%)	35 (23.6%)	50 (29.4%)
Nausea	6 (9.4%)	13 (15.5%)	19 (12.8%)	36 (21.2%)
Abdominal pain	4 (6.3%)	11 (13.1%)	15 (10.1%)	26 (15.3%)
Constipation	4 (6.3%)	10 (11.9%)	14 (9.5%)	25 (14.7%)
Vomiting	5 (7.8%)	8 (9.5%)	13 (8.8%)	19 (11.2%)
Abdominal pain upper	5 (7.8%)	5 (6.0%)	10 (6.8%)	13 (7.6%)
Gastrooesophageal reflux disease	2 (3.1%)	5 (6.0%)	7 (4.7%)	11 (6.5%)
Dyspepsia	2 (3.1%)	5 (6.0%)	7 (4.7%)	8 (4.7%)
Abdominal distension	0	4 (4.8%)	4 (2.7%)	7 (4.1%)
Abdominal discomfort	1 (1.6%)	2 (2.4%)	3 (2.0%)	6 (3.5%)
Ascites	3 (4.7%)	2 (2.4%)	5 (3.4%)	6 (3.5%)
Dry mouth	2 (3.1%)	2 (2.4%)	4 (2.7%)	6 (3.5%)
Rectal haemorrhage	0	3 (3.6%)	3 (2.0%)	5 (2.9%)
Flatulence	0	1 (1.2%)	1 (0.7%)	4 (2.4%)
Haemorrhoids	0	2 (2.4%)	2 (1.4%)	4 (2.4%)
Varices oesophageal	2 (3.1%)	2 (2.4%)	4 (2.7%)	4 (2.4%)
Mouth haemorrhage	0	3 (3.6%)	3 (2.0%)	3 (1.8%)
Toothache	0	2 (2.4%)	2 (1.4%)	3 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Table 3.0211: TEAEs by SOC and PT
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	OL Phase (Week 24 Onward)			Overall Exposed to MMB
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Gastrointestinal disorders (cont)				
Anal incontinence	0	2 (2.4%)	2 (1.4%)	2 (1.2%)
Angular cheilitis	2 (3.1%)	0	2 (1.4%)	2 (1.2%)
Cheilitis	0	1 (1.2%)	1 (0.7%)	2 (1.2%)
Gastritis	1 (1.6%)	1 (1.2%)	2 (1.4%)	2 (1.2%)
Proctalgia	0	0	0	2 (1.2%)
Stomatitis	2 (3.1%)	0	2 (1.4%)	2 (1.2%)
Abdominal rigidity	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Abnormal faeces	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Angina bullosa haemorrhagica	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Aphthous ulcer	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Chronic gastritis	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Colitis	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Defaecation urgency	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Dental caries	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Diverticulum	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Dysphagia	0	0	0	1 (0.6%)
Epigastric discomfort	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Gastric haemorrhage	0	1 (1.2%)	1 (0.7%)	1 (0.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0211: TEAEs by SOC and PT
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	OL Phase (Week 24 Onward)			Overall Exposed to MMB
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Gastrointestinal disorders (cont)				
Gastric ulcer	0	0	0	1 (0.6%)
Gastritis erosive	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Gastrointestinal haemorrhage	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Gingival bleeding	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Gingival ulceration	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Haematemesis	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Haemorrhoidal haemorrhage	0	0	0	1 (0.6%)
Hiatus hernia	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Inguinal hernia	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Intestinal infarction	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Lip pain	0	0	0	1 (0.6%)
Lower gastrointestinal haemorrhage	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Melaena	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Mesenteric vein thrombosis	0	0	0	1 (0.6%)
Mouth ulceration	0	0	0	1 (0.6%)
Odynophagia	0	0	0	1 (0.6%)
Oesophageal varices haemorrhage	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Oral mucosa haematoma	1 (1.6%)	0	1 (0.7%)	1 (0.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0211: TEAEs by SOC and PT
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	OL Phase (Week 24 Onward)			Overall Exposed to MMB
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Gastrointestinal disorders (cont)				
Oral pain	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Pancreatic cyst	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Pancreatic steatosis	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Periodontal disease	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Retching	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Small intestinal haemorrhage	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Tooth impacted	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Infections and infestations	37 (57.8%)	52 (61.9%)	89 (60.1%)	107 (62.9%)
Pneumonia	12 (18.8%)	12 (14.3%)	24 (16.2%)	28 (16.5%)
Urinary tract infection	9 (14.1%)	8 (9.5%)	17 (11.5%)	20 (11.8%)
Upper respiratory tract infection	6 (9.4%)	9 (10.7%)	15 (10.1%)	19 (11.2%)
Nasopharyngitis	4 (6.3%)	5 (6.0%)	9 (6.1%)	10 (5.9%)
Bronchitis	3 (4.7%)	5 (6.0%)	8 (5.4%)	8 (4.7%)
Cystitis	3 (4.7%)	1 (1.2%)	4 (2.7%)	6 (3.5%)
Herpes zoster	3 (4.7%)	1 (1.2%)	4 (2.7%)	6 (3.5%)
Influenza	1 (1.6%)	4 (4.8%)	5 (3.4%)	6 (3.5%)
Sepsis	3 (4.7%)	1 (1.2%)	4 (2.7%)	6 (3.5%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox-gba.sas V.03.05 Output file: t-teae-ol.pdf 29AUG2023: 9:47

Table 3.0211: TEAEs by SOC and PT
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	OL Phase (Week 24 Onward)			Overall Exposed to MMB
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Infections and infestations (cont)				
Sinusitis	2 (3.1%)	4 (4.8%)	6 (4.1%)	6 (3.5%)
Oral herpes	2 (3.1%)	2 (2.4%)	4 (2.7%)	5 (2.9%)
Gastroenteritis	1 (1.6%)	2 (2.4%)	3 (2.0%)	4 (2.4%)
Lower respiratory tract infection	0	1 (1.2%)	1 (0.7%)	4 (2.4%)
Lung infection	3 (4.7%)	0	3 (2.0%)	4 (2.4%)
Respiratory tract infection	1 (1.6%)	1 (1.2%)	2 (1.4%)	3 (1.8%)
Skin infection	0	0	0	3 (1.8%)
Cellulitis	0	1 (1.2%)	1 (0.7%)	2 (1.2%)
Escherichia urinary tract infection	1 (1.6%)	1 (1.2%)	2 (1.4%)	2 (1.2%)
Fungal skin infection	1 (1.6%)	0	1 (0.7%)	2 (1.2%)
Furuncle	2 (3.1%)	0	2 (1.4%)	2 (1.2%)
Genital herpes	1 (1.6%)	1 (1.2%)	2 (1.4%)	2 (1.2%)
Herpes simplex	1 (1.6%)	1 (1.2%)	2 (1.4%)	2 (1.2%)
Laryngitis	0	1 (1.2%)	1 (0.7%)	2 (1.2%)
Localised infection	1 (1.6%)	0	1 (0.7%)	2 (1.2%)
Periodontitis	1 (1.6%)	0	1 (0.7%)	2 (1.2%)
Tonsillitis	1 (1.6%)	1 (1.2%)	2 (1.4%)	2 (1.2%)
Viral infection	1 (1.6%)	1 (1.2%)	2 (1.4%)	2 (1.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox-gba.sas V.03.05 Output file: t-teae-ol.pdf 29AUG2023: 9:47

Table 3.0211: TEAEs by SOC and PT
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	OL Phase (Week 24 Onward)			Overall Exposed to MMB
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Infections and infestations (cont)				
Anal abscess	0	0	0	1 (0.6%)
Bacteraemia	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Borrelia infection	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Clostridium difficile colitis	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Clostridium difficile infection	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Device related infection	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Diverticulitis	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Ear infection	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Enterocolitis infectious	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Erysipelas	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Escherichia infection	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Escherichia sepsis	0	0	0	1 (0.6%)
Eye infection	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Folliculitis	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Fungal infection	0	0	0	1 (0.6%)
Gangrene	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Gastroenteritis viral	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Gastrointestinal candidiasis	0	1 (1.2%)	1 (0.7%)	1 (0.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0211: TEAEs by SOC and PT
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	OL Phase (Week 24 Onward)			Overall Exposed to MMB
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Infections and infestations (cont)				
Gingivitis	0	0	0	1 (0.6%)
Infected dermal cyst	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Infected skin ulcer	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Infection	0	0	0	1 (0.6%)
Labyrinthitis	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Lip infection	0	0	0	1 (0.6%)
Lyme disease	0	0	0	1 (0.6%)
Nasal herpes	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Neuroborreliosis	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Oral candidiasis	0	0	0	1 (0.6%)
Otitis externa	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Otitis media	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Pertussis	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Pharyngitis	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Pneumonia bacterial	0	0	0	1 (0.6%)
Pneumonia viral	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Pyelocystitis	0	0	0	1 (0.6%)
Pyelonephritis	0	1 (1.2%)	1 (0.7%)	1 (0.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0211: TEAEs by SOC and PT
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	OL Phase (Week 24 Onward)			Overall Exposed to MMB
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Infections and infestations (cont)				
Scrotal abscess	0	0	0	1 (0.6%)
Septic shock	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Subcutaneous abscess	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Tetanus	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Tinea versicolour	0	0	0	1 (0.6%)
Tooth abscess	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Tuberculosis	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Varicella zoster virus infection	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Vestibular neuronitis	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Viral uveitis	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Wound infection	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
General disorders and administration site conditions	29 (45.3%)	31 (36.9%)	60 (40.5%)	86 (50.6%)
Fatigue	6 (9.4%)	12 (14.3%)	18 (12.2%)	30 (17.6%)
Pyrexia	11 (17.2%)	6 (7.1%)	17 (11.5%)	25 (14.7%)
Oedema peripheral	8 (12.5%)	3 (3.6%)	11 (7.4%)	16 (9.4%)
Asthenia	5 (7.8%)	5 (6.0%)	10 (6.8%)	14 (8.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0211: TEAEs by SOC and PT
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	OL Phase (Week 24 Onward)			Overall Exposed to MMB
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
General disorders and administration site conditions (cont)				
Chest pain	1 (1.6%)	3 (3.6%)	4 (2.7%)	8 (4.7%)
Influenza like illness	2 (3.1%)	3 (3.6%)	5 (3.4%)	7 (4.1%)
Peripheral swelling	2 (3.1%)	1 (1.2%)	3 (2.0%)	6 (3.5%)
Malaise	1 (1.6%)	2 (2.4%)	3 (2.0%)	5 (2.9%)
Chills	1 (1.6%)	1 (1.2%)	2 (1.4%)	3 (1.8%)
Impaired healing	0	2 (2.4%)	2 (1.4%)	2 (1.2%)
Mucosal inflammation	1 (1.6%)	0	1 (0.7%)	2 (1.2%)
Oedema	0	1 (1.2%)	1 (0.7%)	2 (1.2%)
Pain	0	0	0	2 (1.2%)
Catheter site pain	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Crepitations	0	0	0	1 (0.6%)
Drug withdrawal syndrome	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Early satiety	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Facial pain	0	0	0	1 (0.6%)
Feeling hot	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Gait disturbance	0	0	0	1 (0.6%)
General physical health deterioration	0	1 (1.2%)	1 (0.7%)	1 (0.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Table 3.0211: TEAEs by SOC and PT
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	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
General disorders and administration site conditions (cont)				
Generalised oedema	0	0	0	1 (0.6%)
Multiple organ dysfunction syndrome	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Non-cardiac chest pain	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Sudden death	0	0	0	1 (0.6%)
Swelling	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Xerosis	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Blood and lymphatic system disorders	24 (37.5%)	38 (45.2%)	62 (41.9%)	85 (50.0%)
Thrombocytopenia	12 (18.8%)	16 (19.0%)	28 (18.9%)	43 (25.3%)
Anaemia	16 (25.0%)	15 (17.9%)	31 (20.9%)	41 (24.1%)
Leukocytosis	3 (4.7%)	7 (8.3%)	10 (6.8%)	11 (6.5%)
Neutropenia	2 (3.1%)	3 (3.6%)	5 (3.4%)	8 (4.7%)
Leukopenia	1 (1.6%)	1 (1.2%)	2 (1.4%)	4 (2.4%)
Thrombocytosis	0	3 (3.6%)	3 (2.0%)	3 (1.8%)
Febrile neutropenia	1 (1.6%)	0	1 (0.7%)	2 (1.2%)
Increased tendency to bruise	0	1 (1.2%)	1 (0.7%)	2 (1.2%)
Lymphopenia	1 (1.6%)	1 (1.2%)	2 (1.4%)	2 (1.2%)

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Adverse events were mapped according to MedDRA Version 22.0
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	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Blood and lymphatic system disorders (cont)				
Splenomegaly	1 (1.6%)	0	1 (0.7%)	2 (1.2%)
Haemolysis	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Haemolytic anaemia	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Hypoprothrombinaemia	0	0	0	1 (0.6%)
Neutrophilia	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Splenic haematoma	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Splenic infarction	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Respiratory, thoracic and mediastinal disorders	26 (40.6%)	36 (42.9%)	62 (41.9%)	81 (47.6%)
Cough	12 (18.8%)	16 (19.0%)	28 (18.9%)	39 (22.9%)
Dyspnoea	6 (9.4%)	9 (10.7%)	15 (10.1%)	26 (15.3%)
Epistaxis	5 (7.8%)	3 (3.6%)	8 (5.4%)	11 (6.5%)
Dyspnoea exertional	1 (1.6%)	1 (1.2%)	2 (1.4%)	7 (4.1%)
Pleural effusion	1 (1.6%)	4 (4.8%)	5 (3.4%)	5 (2.9%)
Dysphonia	1 (1.6%)	1 (1.2%)	2 (1.4%)	4 (2.4%)
Respiratory failure	2 (3.1%)	1 (1.2%)	3 (2.0%)	4 (2.4%)
Pulmonary embolism	2 (3.1%)	1 (1.2%)	3 (2.0%)	3 (1.8%)
Rales	1 (1.6%)	0	1 (0.7%)	3 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Table 3.0211: TEAEs by SOC and PT
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	OL Phase (Week 24 Onward)			Overall Exposed to MMB
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Respiratory, thoracic and mediastinal disorders (cont)				
Bronchitis chronic	1 (1.6%)	1 (1.2%)	2 (1.4%)	2 (1.2%)
Chronic obstructive pulmonary disease	0	1 (1.2%)	1 (0.7%)	2 (1.2%)
Hypoxia	1 (1.6%)	0	1 (0.7%)	2 (1.2%)
Pleurisy	0	2 (2.4%)	2 (1.4%)	2 (1.2%)
Productive cough	1 (1.6%)	0	1 (0.7%)	2 (1.2%)
Rhinorrhoea	1 (1.6%)	0	1 (0.7%)	2 (1.2%)
Wheezing	2 (3.1%)	0	2 (1.4%)	2 (1.2%)
Alveolitis	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Asthma	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Emphysema	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Haemoptysis	0	0	0	1 (0.6%)
Hiccups	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Hypoventilation	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Laryngeal inflammation	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Lung consolidation	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Lung disorder	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Nasal dryness	1 (1.6%)	0	1 (0.7%)	1 (0.6%)

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Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
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	OL Phase (Week 24 Onward)			Overall Exposed to MMB
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Respiratory, thoracic and mediastinal disorders (cont)				
Oropharyngeal discomfort	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Oropharyngeal pain	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Pharyngeal ulceration	0	0	0	1 (0.6%)
Pneumonia aspiration	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Pulmonary granuloma	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Pulmonary oedema	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Reflux laryngitis	0	0	0	1 (0.6%)
Sinus congestion	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Tachypnoea	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Throat tightness	0	0	0	1 (0.6%)
Nervous system disorders	27 (42.2%)	32 (38.1%)	59 (39.9%)	79 (46.5%)
Dizziness	6 (9.4%)	14 (16.7%)	20 (13.5%)	34 (20.0%)
Peripheral sensory neuropathy	7 (10.9%)	13 (15.5%)	20 (13.5%)	29 (17.1%)
Headache	2 (3.1%)	3 (3.6%)	5 (3.4%)	15 (8.8%)
Paraesthesia	3 (4.7%)	5 (6.0%)	8 (5.4%)	13 (7.6%)
Hypoaesthesia	5 (7.8%)	2 (2.4%)	7 (4.7%)	7 (4.1%)

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Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Nervous system disorders (cont)				
Balance disorder	3 (4.7%)	1 (1.2%)	4 (2.7%)	6 (3.5%)
Amnesia	1 (1.6%)	2 (2.4%)	3 (2.0%)	4 (2.4%)
Syncope	1 (1.6%)	1 (1.2%)	2 (1.4%)	4 (2.4%)
Presyncope	1 (1.6%)	0	1 (0.7%)	3 (1.8%)
Somnolence	1 (1.6%)	1 (1.2%)	2 (1.4%)	3 (1.8%)
Cerebrovascular accident	2 (3.1%)	0	2 (1.4%)	2 (1.2%)
Dysgeusia	1 (1.6%)	1 (1.2%)	2 (1.4%)	2 (1.2%)
Lethargy	1 (1.6%)	1 (1.2%)	2 (1.4%)	2 (1.2%)
Memory impairment	0	1 (1.2%)	1 (0.7%)	2 (1.2%)
Sensory disturbance	1 (1.6%)	1 (1.2%)	2 (1.4%)	2 (1.2%)
Taste disorder	0	0	0	2 (1.2%)
Transient ischaemic attack	1 (1.6%)	1 (1.2%)	2 (1.4%)	2 (1.2%)
Ageusia	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Ataxia	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Burning sensation	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Cerebellar stroke	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Cerebral atrophy	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Cerebral ischaemia	0	0	0	1 (0.6%)

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Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Nervous system disorders (cont)				
Cerebral microangiopathy	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Cerebrovascular insufficiency	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Dementia	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Demyelination	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Dysaesthesia	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Haemorrhagic stroke	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Lacunar infarction	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Leukoencephalopathy	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Myotonia	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Neuropathy peripheral	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Parkinson's disease	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Peripheral sensorimotor neuropathy	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Restless legs syndrome	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Sciatica	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Sinus headache	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Tremor	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Metabolism and nutrition disorders	26 (40.6%)	35 (41.7%)	61 (41.2%)	78 (45.9%)

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Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Metabolism and nutrition disorders (cont)				
Vitamin B1 deficiency	7 (10.9%)	8 (9.5%)	15 (10.1%)	19 (11.2%)
Decreased appetite	6 (9.4%)	7 (8.3%)	13 (8.8%)	17 (10.0%)
Hyperuricaemia	4 (6.3%)	8 (9.5%)	12 (8.1%)	17 (10.0%)
Hyperkalaemia	8 (12.5%)	1 (1.2%)	9 (6.1%)	11 (6.5%)
Hypokalaemia	2 (3.1%)	3 (3.6%)	5 (3.4%)	8 (4.7%)
Hypomagnesaemia	1 (1.6%)	1 (1.2%)	2 (1.4%)	7 (4.1%)
Hypocalcaemia	1 (1.6%)	1 (1.2%)	2 (1.4%)	5 (2.9%)
Dehydration	1 (1.6%)	2 (2.4%)	3 (2.0%)	4 (2.4%)
Diabetes mellitus	0	4 (4.8%)	4 (2.7%)	4 (2.4%)
Gout	2 (3.1%)	1 (1.2%)	3 (2.0%)	4 (2.4%)
Hyperglycaemia	1 (1.6%)	2 (2.4%)	3 (2.0%)	4 (2.4%)
Vitamin D deficiency	1 (1.6%)	1 (1.2%)	2 (1.4%)	4 (2.4%)
Hypoalbuminaemia	1 (1.6%)	1 (1.2%)	2 (1.4%)	3 (1.8%)
Hyponatraemia	1 (1.6%)	1 (1.2%)	2 (1.4%)	3 (1.8%)
Iron overload	1 (1.6%)	1 (1.2%)	2 (1.4%)	3 (1.8%)
Hypoglycaemia	0	1 (1.2%)	1 (0.7%)	2 (1.2%)
Vitamin B complex deficiency	1 (1.6%)	0	1 (0.7%)	2 (1.2%)
Abnormal loss of weight	0	1 (1.2%)	1 (0.7%)	1 (0.6%)

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Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Metabolism and nutrition disorders (cont)				
Dyslipidaemia	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Electrolyte imbalance	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Fluid overload	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Fluid retention	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Haemosiderosis	0	0	0	1 (0.6%)
Hypercalcaemia	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Hypernatraemia	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Hypertriglyceridaemia	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Hypophosphataemia	0	0	0	1 (0.6%)
Iron deficiency	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Vitamin K deficiency	0	0	0	1 (0.6%)
Skin and subcutaneous tissue disorders	24 (37.5%)	25 (29.8%)	49 (33.1%)	62 (36.5%)
Rash	7 (10.9%)	5 (6.0%)	12 (8.1%)	16 (9.4%)
Night sweats	7 (10.9%)	4 (4.8%)	11 (7.4%)	15 (8.8%)
Pruritus	2 (3.1%)	8 (9.5%)	10 (6.8%)	11 (6.5%)
Hyperhidrosis	0	4 (4.8%)	4 (2.7%)	4 (2.4%)
Ecchymosis	1 (1.6%)	1 (1.2%)	2 (1.4%)	3 (1.8%)

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Table 3.0211: TEAEs by SOC and PT
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SAF-Anemic Analysis Set

	OL Phase (Week 24 Onward)			Overall Exposed to MMB
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Skin and subcutaneous tissue disorders (cont)				
Erythema	1 (1.6%)	1 (1.2%)	2 (1.4%)	3 (1.8%)
Petechiae	1 (1.6%)	0	1 (0.7%)	3 (1.8%)
Rash maculo-papular	0	1 (1.2%)	1 (0.7%)	3 (1.8%)
Actinic keratosis	2 (3.1%)	0	2 (1.4%)	2 (1.2%)
Alopecia	0	1 (1.2%)	1 (0.7%)	2 (1.2%)
Blister	0	1 (1.2%)	1 (0.7%)	2 (1.2%)
Dermatitis contact	0	0	0	2 (1.2%)
Rash generalised	1 (1.6%)	1 (1.2%)	2 (1.4%)	2 (1.2%)
Rash macular	0	1 (1.2%)	1 (0.7%)	2 (1.2%)
Blood blister	0	0	0	1 (0.6%)
Cold sweat	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Dermal cyst	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Dermatitis	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Dermatitis allergic	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Dermatosis	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Drug eruption	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Hyperkeratosis	0	0	0	1 (0.6%)
Hypersensitivity vasculitis	0	1 (1.2%)	1 (0.7%)	1 (0.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0211: TEAEs by SOC and PT
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	OL Phase (Week 24 Onward)			Overall Exposed to MMB
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Skin and subcutaneous tissue disorders (cont)				
Ingrowing nail	0	0	0	1 (0.6%)
Lichenoid keratosis	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Nail discolouration	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Papule	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Pruritus generalised	0	0	0	1 (0.6%)
Purpura	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Rash papular	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Skin disorder	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Skin exfoliation	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Skin fragility	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Skin haemorrhage	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Skin lesion	0	0	0	1 (0.6%)
Telangiectasia	0	0	0	1 (0.6%)
Toxic skin eruption	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Musculoskeletal and connective tissue disorders	16 (25.0%)	30 (35.7%)	46 (31.1%)	61 (35.9%)
Pain in extremity	7 (10.9%)	6 (7.1%)	13 (8.8%)	21 (12.4%)
Back pain	4 (6.3%)	11 (13.1%)	15 (10.1%)	20 (11.8%)

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Table 3.0211: TEAEs by SOC and PT
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	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Musculoskeletal and connective tissue disorders (cont)				
Arthralgia	4 (6.3%)	4 (4.8%)	8 (5.4%)	10 (5.9%)
Bone pain	3 (4.7%)	3 (3.6%)	6 (4.1%)	8 (4.7%)
Musculoskeletal pain	1 (1.6%)	2 (2.4%)	3 (2.0%)	5 (2.9%)
Muscle spasms	0	2 (2.4%)	2 (1.4%)	4 (2.4%)
Muscular weakness	2 (3.1%)	1 (1.2%)	3 (2.0%)	3 (1.8%)
Myalgia	1 (1.6%)	1 (1.2%)	2 (1.4%)	3 (1.8%)
Arthritis	1 (1.6%)	1 (1.2%)	2 (1.4%)	2 (1.2%)
Groin pain	0	0	0	2 (1.2%)
Osteoarthritis	1 (1.6%)	1 (1.2%)	2 (1.4%)	2 (1.2%)
Pain in jaw	1 (1.6%)	0	1 (0.7%)	2 (1.2%)
Spinal pain	0	1 (1.2%)	1 (0.7%)	2 (1.2%)
Arthritis reactive	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Bone lesion	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Bursal fluid accumulation	0	0	0	1 (0.6%)
Chondrocalcinosis pyrophosphate	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Costochondritis	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Fasciitis	0	1 (1.2%)	1 (0.7%)	1 (0.6%)

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Table 3.0211: TEAEs by SOC and PT
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
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	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Musculoskeletal and connective tissue disorders (cont)				
Flank pain	0	0	0	1 (0.6%)
Gouty arthritis	0	0	0	1 (0.6%)
Intervertebral disc protrusion	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Joint effusion	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Joint swelling	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Mobility decreased	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Muscle haemorrhage	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Musculoskeletal chest pain	0	0	0	1 (0.6%)
Musculoskeletal stiffness	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Neck pain	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Osteoporosis	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Osteosclerosis	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Rotator cuff syndrome	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Tendonitis	0	0	0	1 (0.6%)
Investigations	17 (26.6%)	18 (21.4%)	35 (23.6%)	49 (28.8%)
Alanine aminotransferase increased	3 (4.7%)	4 (4.8%)	7 (4.7%)	13 (7.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Table 3.0211: TEAEs by SOC and PT
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
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	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Investigations (cont)				
Blood creatinine increased	6 (9.4%)	5 (6.0%)	11 (7.4%)	12 (7.1%)
Gamma-glutamyltransferase increased	1 (1.6%)	4 (4.8%)	5 (3.4%)	9 (5.3%)
Aspartate aminotransferase increased	1 (1.6%)	3 (3.6%)	4 (2.7%)	7 (4.1%)
Weight decreased	3 (4.7%)	1 (1.2%)	4 (2.7%)	6 (3.5%)
Blood bilirubin increased	1 (1.6%)	2 (2.4%)	3 (2.0%)	4 (2.4%)
Creatinine renal clearance decreased	2 (3.1%)	1 (1.2%)	3 (2.0%)	4 (2.4%)
Weight increased	1 (1.6%)	1 (1.2%)	2 (1.4%)	4 (2.4%)
Activated partial thromboplastin time prolonged	0	2 (2.4%)	2 (1.4%)	2 (1.2%)
Blood alkaline phosphatase increased	0	0	0	2 (1.2%)
Electrocardiogram QT prolonged	1 (1.6%)	0	1 (0.7%)	2 (1.2%)
Protein total increased	1 (1.6%)	0	1 (0.7%)	2 (1.2%)
Transaminases increased	0	1 (1.2%)	1 (0.7%)	2 (1.2%)
Antiphospholipid antibodies positive	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Blast cell count increased	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Blood bicarbonate decreased	0	0	0	1 (0.6%)
Blood chloride increased	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Blood creatine phosphokinase increased	0	1 (1.2%)	1 (0.7%)	1 (0.6%)

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Table 3.0211: TEAEs by SOC and PT
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	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Investigations (cont)				
Blood folate decreased	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Blood lactate dehydrogenase increased	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Blood lactic acid increased	0	0	0	1 (0.6%)
Blood pressure increased	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Chest X-ray abnormal	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Computerised tomogram pelvis abnormal	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Electrocardiogram ST segment depression	0	0	0	1 (0.6%)
International normalised ratio increased	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Liver function test abnormal	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Lymph node palpable	0	0	0	1 (0.6%)
Prothrombin time prolonged	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Serum ferritin increased	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Vitamin B1 decreased	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Renal and urinary disorders	17 (26.6%)	16 (19.0%)	33 (22.3%)	44 (25.9%)
Acute kidney injury	3 (4.7%)	3 (3.6%)	6 (4.1%)	8 (4.7%)
Chronic kidney disease	3 (4.7%)	2 (2.4%)	5 (3.4%)	6 (3.5%)
Haematuria	2 (3.1%)	2 (2.4%)	4 (2.7%)	5 (2.9%)

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Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Renal and urinary disorders (cont)				
Renal failure	1 (1.6%)	3 (3.6%)	4 (2.7%)	5 (2.9%)
Renal impairment	3 (4.7%)	0	3 (2.0%)	5 (2.9%)
Dysuria	1 (1.6%)	1 (1.2%)	2 (1.4%)	4 (2.4%)
Nocturia	1 (1.6%)	1 (1.2%)	2 (1.4%)	4 (2.4%)
Nephrolithiasis	0	1 (1.2%)	1 (0.7%)	2 (1.2%)
Pollakiuria	0	0	0	2 (1.2%)
Renal colic	0	2 (2.4%)	2 (1.4%)	2 (1.2%)
Chromaturia	0	0	0	1 (0.6%)
Hypertensive nephropathy	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Micturition disorder	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Nephropathy	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Proteinuria	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Renal cyst	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Renal disorder	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Renal tubular necrosis	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Urinary incontinence	0	0	0	1 (0.6%)
Urinary retention	0	0	0	1 (0.6%)

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Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Vascular disorders	14 (21.9%)	16 (19.0%)	30 (20.3%)	43 (25.3%)
Hypotension	3 (4.7%)	3 (3.6%)	6 (4.1%)	17 (10.0%)
Hypertension	5 (7.8%)	6 (7.1%)	11 (7.4%)	12 (7.1%)
Haematoma	3 (4.7%)	2 (2.4%)	5 (3.4%)	6 (3.5%)
Flushing	0	1 (1.2%)	1 (0.7%)	5 (2.9%)
Hot flush	1 (1.6%)	1 (1.2%)	2 (1.4%)	3 (1.8%)
Aortic stenosis	1 (1.6%)	1 (1.2%)	2 (1.4%)	2 (1.2%)
Arteriosclerosis	0	2 (2.4%)	2 (1.4%)	2 (1.2%)
Peripheral arterial occlusive disease	0	1 (1.2%)	1 (0.7%)	2 (1.2%)
Aortic arteriosclerosis	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Deep vein thrombosis	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Orthostatic hypotension	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Phlebitis	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Poor venous access	0	0	0	1 (0.6%)
Thrombophlebitis superficial	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Cardiac disorders	12 (18.8%)	13 (15.5%)	25 (16.9%)	35 (20.6%)
Atrial fibrillation	6 (9.4%)	5 (6.0%)	11 (7.4%)	16 (9.4%)
Cardiac failure	2 (3.1%)	3 (3.6%)	5 (3.4%)	7 (4.1%)

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Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Cardiac disorders (cont)				
Angina pectoris	0	2 (2.4%)	2 (1.4%)	3 (1.8%)
Palpitations	1 (1.6%)	1 (1.2%)	2 (1.4%)	3 (1.8%)
Atrial flutter	1 (1.6%)	1 (1.2%)	2 (1.4%)	2 (1.2%)
Cardiac failure congestive	1 (1.6%)	0	1 (0.7%)	2 (1.2%)
Mitral valve incompetence	1 (1.6%)	1 (1.2%)	2 (1.4%)	2 (1.2%)
Tachycardia	1 (1.6%)	0	1 (0.7%)	2 (1.2%)
Acute myocardial infarction	0	0	0	1 (0.6%)
Atrioventricular block complete	0	0	0	1 (0.6%)
Atrioventricular block first degree	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Bradycardia	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Cardiac arrest	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Cardiac valve disease	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Cardiomegaly	0	0	0	1 (0.6%)
Cardiomyopathy	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Extrasystoles	0	0	0	1 (0.6%)
Myocardial infarction	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Pericardial effusion	0	0	0	1 (0.6%)
Sinus bradycardia	1 (1.6%)	0	1 (0.7%)	1 (0.6%)

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Table 3.0211: TEAEs by SOC and PT
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Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Cardiac disorders (cont)				
Supraventricular extrasystoles	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Supraventricular tachycardia	0	0	0	1 (0.6%)
Injury, poisoning and procedural complications	13 (20.3%)	12 (14.3%)	25 (16.9%)	34 (20.0%)
Contusion	4 (6.3%)	2 (2.4%)	6 (4.1%)	13 (7.6%)
Fall	3 (4.7%)	6 (7.1%)	9 (6.1%)	13 (7.6%)
Limb injury	2 (3.1%)	1 (1.2%)	3 (2.0%)	5 (2.9%)
Post procedural haemorrhage	1 (1.6%)	1 (1.2%)	2 (1.4%)	2 (1.2%)
Procedural pain	0	1 (1.2%)	1 (0.7%)	2 (1.2%)
Spinal compression fracture	1 (1.6%)	1 (1.2%)	2 (1.4%)	2 (1.2%)
Wound	1 (1.6%)	0	1 (0.7%)	2 (1.2%)
Dental restoration failure	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Facial bones fracture	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Febrile nonhaemolytic transfusion reaction	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Head injury	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Limb crushing injury	0	0	0	1 (0.6%)
Muscle strain	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Patella fracture	0	1 (1.2%)	1 (0.7%)	1 (0.6%)

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Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0211: TEAEs by SOC and PT
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	OL Phase (Week 24 Onward)			Overall Exposed to MMB
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Injury, poisoning and procedural complications (cont)				
Post procedural complication	0	0	0	1 (0.6%)
Post procedural contusion	0	0	0	1 (0.6%)
Post procedural inflammation	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Procedural nausea	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Skin abrasion	0	0	0	1 (0.6%)
Skin injury	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Skin laceration	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Spinal fracture	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Subcutaneous haematoma	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Subdural haemorrhage	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Traumatic haemothorax	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Eye disorders	14 (21.9%)	9 (10.7%)	23 (15.5%)	31 (18.2%)
Cataract cortical	2 (3.1%)	2 (2.4%)	4 (2.7%)	5 (2.9%)
Cataract nuclear	5 (7.8%)	0	5 (3.4%)	5 (2.9%)
Vision blurred	1 (1.6%)	1 (1.2%)	2 (1.4%)	5 (2.9%)
Conjunctival haemorrhage	3 (4.7%)	1 (1.2%)	4 (2.7%)	4 (2.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox-gba.sas V.03.05 Output file: t-teae-ol.pdf 29AUG2023: 9:47

Table 3.0211: TEAEs by SOC and PT
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	OL Phase (Week 24 Onward)			Overall Exposed to MMB
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Eye disorders (cont)				
Retinal haemorrhage	2 (3.1%)	0	2 (1.4%)	3 (1.8%)
Cataract	0	1 (1.2%)	1 (0.7%)	2 (1.2%)
Dry eye	1 (1.6%)	1 (1.2%)	2 (1.4%)	2 (1.2%)
Eye haemorrhage	2 (3.1%)	0	2 (1.4%)	2 (1.2%)
Keratitis	0	1 (1.2%)	1 (0.7%)	2 (1.2%)
Lacrimation increased	0	0	0	2 (1.2%)
Cataract subcapsular	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Diplopia	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Erythema of eyelid	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Eye pain	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Eyelid oedema	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Eyelid ptosis	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Hyalosis asteroid	0	0	0	1 (0.6%)
Macular degeneration	0	0	0	1 (0.6%)
Periorbital oedema	0	0	0	1 (0.6%)
Retinal detachment	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Visual acuity reduced	0	0	0	1 (0.6%)
Visual impairment	1 (1.6%)	0	1 (0.7%)	1 (0.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox-gba.sas V.03.05 Output file: t-teae-ol.pdf 29AUG2023: 9:47

Table 3.0211: TEAEs by SOC and PT
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	OL Phase (Week 24 Onward)			Overall Exposed to MMB
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Eye disorders (cont)				
Vitreous floaters	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	14 (21.9%)	11 (13.1%)	25 (16.9%)	28 (16.5%)
Acute myeloid leukaemia	3 (4.7%)	1 (1.2%)	4 (2.7%)	5 (2.9%)
Basal cell carcinoma	2 (3.1%)	1 (1.2%)	3 (2.0%)	3 (1.8%)
Squamous cell carcinoma of skin	1 (1.6%)	2 (2.4%)	3 (2.0%)	3 (1.8%)
Uterine cancer	1 (1.6%)	0	1 (0.7%)	2 (1.2%)
Angiomyolipoma	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Bowen's disease	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Chronic myeloid leukaemia	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Eyelid tumour	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Haemangioma of bone	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Langerhans cell sarcoma	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Leukoerythroblastosis	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Malignant melanoma	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Metastatic squamous cell carcinoma	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Ovarian clear cell carcinoma	0	0	0	1 (0.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox-gba.sas V.03.05 Output file: t-teae-ol.pdf 29AUG2023: 9:47

Table 3.0211: TEAEs by SOC and PT
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	OL Phase (Week 24 Onward)			Overall Exposed to MMB
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Rectal cancer	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Seborrhoeic keratosis	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Seminoma	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Sinonasal papilloma	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Skin papilloma	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Splenic marginal zone lymphoma	0	0	0	1 (0.6%)
Transformation to acute myeloid leukaemia	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Tumour associated fever	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Uterine leiomyoma	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Psychiatric disorders	14 (21.9%)	9 (10.7%)	23 (15.5%)	27 (15.9%)
Insomnia	7 (10.9%)	4 (4.8%)	11 (7.4%)	12 (7.1%)
Depression	5 (7.8%)	1 (1.2%)	6 (4.1%)	7 (4.1%)
Anxiety	3 (4.7%)	0	3 (2.0%)	6 (3.5%)
Confusional state	2 (3.1%)	1 (1.2%)	3 (2.0%)	4 (2.4%)
Libido decreased	1 (1.6%)	1 (1.2%)	2 (1.4%)	2 (1.2%)
Delusion	0	1 (1.2%)	1 (0.7%)	1 (0.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox-gba.sas V.03.05 Output file: t-teae-ol.pdf 29AUG2023: 9:47

Table 3.0211: TEAEs by SOC and PT
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	OL Phase (Week 24 Onward)			Overall Exposed to MMB
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Psychiatric disorders (cont)				
Disorientation	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Hallucination	0	0	0	1 (0.6%)
Mental status changes	0	0	0	1 (0.6%)
Sleep disorder	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Suicidal ideation	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Ear and labyrinth disorders	4 (6.3%)	6 (7.1%)	10 (6.8%)	14 (8.2%)
Vertigo	1 (1.6%)	4 (4.8%)	5 (3.4%)	8 (4.7%)
Hypoacusis	0	1 (1.2%)	1 (0.7%)	2 (1.2%)
Deafness	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Deafness unilateral	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Motion sickness	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Sudden hearing loss	1 (1.6%)	0	1 (0.7%)	1 (0.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0211: TEAEs by SOC and PT
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	OL Phase (Week 24 Onward)			Overall Exposed to MMB
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Hepatobiliary disorders	5 (7.8%)	5 (6.0%)	10 (6.8%)	10 (5.9%)
Cholelithiasis	2 (3.1%)	1 (1.2%)	3 (2.0%)	3 (1.8%)
Liver disorder	1 (1.6%)	1 (1.2%)	2 (1.4%)	2 (1.2%)
Ocular icterus	1 (1.6%)	1 (1.2%)	2 (1.4%)	2 (1.2%)
Portal hypertension	0	2 (2.4%)	2 (1.4%)	2 (1.2%)
Hepatic function abnormal	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Hepatic steatosis	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Reproductive system and breast disorders	3 (4.7%)	4 (4.8%)	7 (4.7%)	10 (5.9%)
Benign prostatic hyperplasia	2 (3.1%)	3 (3.6%)	5 (3.4%)	6 (3.5%)
Postmenopausal haemorrhage	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Uterine haemorrhage	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Vaginal haemorrhage	0	0	0	1 (0.6%)
Vulvovaginal pain	0	0	0	1 (0.6%)
Endocrine disorders	0	3 (3.6%)	3 (2.0%)	3 (1.8%)
Goitre	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Hypothyroidism	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Thyroiditis	0	1 (1.2%)	1 (0.7%)	1 (0.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox-gba.sas V.03.05 Output file: t-teae-ol.pdf 29AUG2023: 9:47

Table 3.0211: TEAEs by SOC and PT
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	OL Phase (Week 24 Onward)			Overall Exposed to MMB
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE	59 (92.2%)	83 (98.8%)	142 (95.9%)	166 (97.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class And Preferred Term				
Immune system disorders	1 (1.6%)	1 (1.2%)	2 (1.4%)	2 (1.2%)
Drug hypersensitivity	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Seasonal allergy	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Surgical and medical procedures	0	0	0	1 (0.6%)
Tooth extraction	0	0	0	1 (0.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

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Table 3.0301: TEAEs with Grade 3 or more by SOC and PT
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)			
				Continuing	Switch		
SOC	MMB	RUX	Total	(MMB->MMB)	(RUX->MMB)	Total	
PT	(N=86)	(N=94)	(N=180)	(N=64)	(N=84)	(N=148)	
Any TEAE of Grade 3 or more							
Number of Subjects With Any Event	42 (48.8%)	52 (55.3%)	94 (52.2%)	46 (71.9%)	53 (63.1%)	99 (66.9%)	
Unadjusted Relative Risk (95% CI)	0.88 (0.67, 1.17)						
p-value [1]	0.39						
Unadjusted Odds Ratio (95% CI)	0.77 (0.43, 1.39)						
p-value [1]	0.38						
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.21, 0.08)						
Blood and lymphatic system disorders							
Any Event	19 (22.1%)	33 (35.1%)	52 (28.9%)	19 (29.7%)	20 (23.8%)	39 (26.4%)	
Unadjusted Relative Risk (95% CI)	0.63 (0.39, 1.02)						
p-value [1]	0.060						
Unadjusted Odds Ratio (95% CI)	0.52 (0.27, 1.02)						
p-value [1]	0.056						
Unadjusted Absolute Risk Difference (95% CI)	-0.13 (-0.26, 0.00)						
Blood and lymphatic system disorders							
Anaemia	10 (11.6%)	26 (27.7%)	36 (20.0%)	13 (20.3%)	6 (7.1%)	19 (12.8%)	
Unadjusted Relative Risk (95% CI)	0.42 (0.22, 0.82)						
p-value [1]	0.011						
Unadjusted Odds Ratio (95% CI)	0.34 (0.15, 0.77)						
p-value [1]	0.009						
Unadjusted Absolute Risk Difference (95% CI)	-0.16 (-0.27, -0.05)						

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gge3-gba.sas V.03.05 Output file: t-ae-socpt-gge3-gba.pdf 24AUG2023:12:46

Table 3.0301: TEAEs with Grade 3 or more by SOC and PT
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	RUX	Total	(MMB->MMB)	(RUX->MMB)	Total
PT	(N=86)	(N=94)	(N=180)	(N=64)	(N=84)	(N=148)
Blood and lymphatic system disorders						
Thrombocytopenia	9 (10.5%)	6 (6.4%)	15 (8.3%)	8 (12.5%)	11 (13.1%)	19 (12.8%)
Unadjusted Relative Risk (95% CI)	1.64 (0.61, 4.42)					
p-value [1]	0.33					
Unadjusted Odds Ratio (95% CI)	1.71 (0.58, 5.03)					
p-value [1]	0.33					
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.04, 0.12)					
Blood and lymphatic system disorders						
Neutropenia	3 (3.5%)	7 (7.4%)	10 (5.6%)	1 (1.6%)	3 (3.6%)	4 (2.7%)
Unadjusted Relative Risk (95% CI)	0.47 (0.13, 1.75)					
p-value [1]	0.26					
Unadjusted Odds Ratio (95% CI)	0.45 (0.11, 1.80)					
p-value [1]	0.26					
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.11, 0.03)					
Infections and infestations						
Any Event	11 (12.8%)	6 (6.4%)	17 (9.4%)	17 (26.6%)	19 (22.6%)	36 (24.3%)
Unadjusted Relative Risk (95% CI)	2.00 (0.77, 5.19)					
p-value [1]	0.15					
Unadjusted Odds Ratio (95% CI)	2.15 (0.76, 6.09)					
p-value [1]	0.15					
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.02, 0.15)					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019

Table 3.0301: TEAEs with Grade 3 or more by SOC and PT
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	RUX	Total	(MMB->MMB)	(RUX->MMB)	Total
PT	(N=86)	(N=94)	(N=180)	(N=64)	(N=84)	(N=148)
Infections and infestations						
Pneumonia	4 (4.7%)	3 (3.2%)	7 (3.9%)	10 (15.6%)	8 (9.5%)	18 (12.2%)
Unadjusted Relative Risk (95% CI)	1.46 (0.34, 6.33)					
p-value [1]	0.62					
Unadjusted Odds Ratio (95% CI)	1.48 (0.32, 6.81)					
p-value [1]	0.61					
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.04, 0.07)					
Metabolism and nutrition disorders						
Any Event	8 (9.3%)	4 (4.3%)	12 (6.7%)	9 (14.1%)	5 (6.0%)	14 (9.5%)
Unadjusted Relative Risk (95% CI)	2.19 (0.68, 7.00)					
p-value [1]	0.19					
Unadjusted Odds Ratio (95% CI)	2.31 (0.67, 7.96)					
p-value [1]	0.19					
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.02, 0.12)					
Metabolism and nutrition disorders						
Hyperkalaemia	2 (2.3%)	2 (2.1%)	4 (2.2%)	5 (7.8%)	0	5 (3.4%)
Unadjusted Relative Risk (95% CI)	1.09 (0.16, 7.59)					
p-value [1]	0.93					
Unadjusted Odds Ratio (95% CI)	1.10 (0.15, 7.95)					
p-value [1]	0.93					
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.04, 0.05)					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019

Table 3.0301: TEAEs with Grade 3 or more by SOC and PT
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	RUX	Total	(MMB->MMB)	(RUX->MMB)	Total
PT	(N=86)	(N=94)	(N=180)	(N=64)	(N=84)	(N=148)
Cardiac disorders						
Any Event	6 (7.0%)	4 (4.3%)	10 (5.6%)	5 (7.8%)	9 (10.7%)	14 (9.5%)
Unadjusted Relative Risk (95% CI)	1.64 (0.48, 5.61)					
p-value [1]	0.43					
Unadjusted Odds Ratio (95% CI)	1.69 (0.46, 6.20)					
p-value [1]	0.43					
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.04, 0.09)					
Gastrointestinal disorders						
Any Event	6 (7.0%)	4 (4.3%)	10 (5.6%)	2 (3.1%)	10 (11.9%)	12 (8.1%)
Unadjusted Relative Risk (95% CI)	1.64 (0.48, 5.61)					
p-value [1]	0.43					
Unadjusted Odds Ratio (95% CI)	1.69 (0.46, 6.20)					
p-value [1]	0.43					
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.04, 0.09)					
Investigations						
Any Event	5 (5.8%)	3 (3.2%)	8 (4.4%)	5 (7.8%)	0	5 (3.4%)
Unadjusted Relative Risk (95% CI)	1.82 (0.45, 7.40)					
p-value [1]	0.40					
Unadjusted Odds Ratio (95% CI)	1.87 (0.43, 8.08)					
p-value [1]	0.40					
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.03, 0.09)					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019

Table 3.0301: TEAEs with Grade 3 or more by SOC and PT
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	RUX	Total	(MMB->MMB)	(RUX->MMB)	Total
PT	(N=86)	(N=94)	(N=180)	(N=64)	(N=84)	(N=148)
Renal and urinary disorders						
Any Event	4 (4.7%)	3 (3.2%)	7 (3.9%)	5 (7.8%)	7 (8.3%)	12 (8.1%)
Unadjusted Relative Risk (95% CI)	1.46 (0.34, 6.33)					
p-value [1]	0.62					
Unadjusted Odds Ratio (95% CI)	1.48 (0.32, 6.81)					
p-value [1]	0.61					
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.04, 0.07)					
Respiratory, thoracic and mediastinal disorders						
Any Event	4 (4.7%)	2 (2.1%)	6 (3.3%)	4 (6.3%)	8 (9.5%)	12 (8.1%)
Unadjusted Relative Risk (95% CI)	2.19 (0.41, 11.64)					
p-value [1]	0.36					
Unadjusted Odds Ratio (95% CI)	2.24 (0.40, 12.57)					
p-value [1]	0.36					
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.03, 0.08)					
Respiratory, thoracic and mediastinal disorders						
Dyspnoea	0	1 (1.1%)	1 (0.6%)	0	5 (6.0%)	5 (3.4%)
Unadjusted Relative Risk (95% CI)	0.36 (0.02, 8.82)					
p-value [1]	0.53					
Unadjusted Odds Ratio (95% CI)	0.36 (0.01, 8.96)					
p-value [1]	0.53					
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.04, 0.02)					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019

Table 3.0301: TEAEs with Grade 3 or more by SOC and PT
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
SOC PT	MMB (N=86)	RUX (N=94)	Total (N=180)	(MMB->MMB) (N=64)	(RUX->MMB) (N=84)	Total (N=148)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event	3 (3.5%)	2 (2.1%)	5 (2.8%)	8 (12.5%)	5 (6.0%)	13 (8.8%)
Unadjusted Relative Risk (95% CI)	1.64 (0.28, 9.58)					
p-value [1]	0.58					
Unadjusted Odds Ratio (95% CI)	1.66 (0.27, 10.20)					
p-value [1]	0.58					
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.03, 0.06)					
Nervous system disorders						
Any Event	3 (3.5%)	2 (2.1%)	5 (2.8%)	9 (14.1%)	5 (6.0%)	14 (9.5%)
Unadjusted Relative Risk (95% CI)	1.64 (0.28, 9.58)					
p-value [1]	0.58					
Unadjusted Odds Ratio (95% CI)	1.66 (0.27, 10.20)					
p-value [1]	0.58					
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.03, 0.06)					
Vascular disorders						
Any Event	3 (3.5%)	5 (5.3%)	8 (4.4%)	4 (6.3%)	4 (4.8%)	8 (5.4%)
Unadjusted Relative Risk (95% CI)	0.66 (0.16, 2.66)					
p-value [1]	0.56					
Unadjusted Odds Ratio (95% CI)	0.64 (0.15, 2.78)					
p-value [1]	0.55					
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.08, 0.04)					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019

Table 3.0301: TEAEs with Grade 3 or more by SOC and PT
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)			
				Continuing	Switch		
SOC	MMB	RUX	Total	(MMB->MMB)	(RUX->MMB)	Total	
PT	(N=86)	(N=94)	(N=180)	(N=64)	(N=84)	(N=148)	
Eye disorders							
Any Event	0	0	0	4 (6.3%)	1 (1.2%)	5 (3.4%)	
Unadjusted Relative Risk (95% CI)	NE						
p-value [1]	NE						
Unadjusted Odds Ratio (95% CI)	NE						
p-value [1]	NE						
Unadjusted Absolute Risk Difference (95% CI)	NE						

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019

Table 3.1701: TEAEs with Grade 2 or less by SOC and PT
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)			
				Continuing	Switch		
SOC	MMB	RUX	Total	(MMB->MMB)	(RUX->MMB)	Total	
PT	(N=86)	(N=94)	(N=180)	(N=64)	(N=84)	(N=148)	
Any TEAE of Grade 2 or less							
Number of Subjects With Any Event	77 (89.5%)	90 (95.7%)	167 (92.8%)	58 (90.6%)	81 (96.4%)	139 (93.9%)	
Unadjusted Relative Risk (95% CI)	0.94 (0.86, 1.02)						
p-value [1]	0.12						
Unadjusted Odds Ratio (95% CI)	0.38 (0.11, 1.28)						
p-value [1]	0.12						
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.14, 0.01)						
Gastrointestinal disorders							
Any Event	44 (51.2%)	36 (38.3%)	80 (44.4%)	29 (45.3%)	52 (61.9%)	81 (54.7%)	
Unadjusted Relative Risk (95% CI)	1.34 (0.96, 1.86)						
p-value [1]	0.085						
Unadjusted Odds Ratio (95% CI)	1.69 (0.93, 3.05)						
p-value [1]	0.084						
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.02, 0.27)						
Gastrointestinal disorders							
Nausea	19 (22.1%)	3 (3.2%)	22 (12.2%)	6 (9.4%)	13 (15.5%)	19 (12.8%)	
Unadjusted Relative Risk (95% CI)	6.92 (2.12, 22.57)						
p-value [1]	0.001						
Unadjusted Odds Ratio (95% CI)	8.60 (2.45, 30.26)						
p-value [1]	<0.001						
Unadjusted Absolute Risk Difference (95% CI)	0.19 (0.09, 0.28)						

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019

Table 3.1701: TEAEs with Grade 2 or less by SOC and PT
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	RUX	Total	(MMB->MMB)	(RUX->MMB)	Total
PT	(N=86)	(N=94)	(N=180)	(N=64)	(N=84)	(N=148)
Gastrointestinal disorders						
Diarrhoea	18 (20.9%)	18 (19.1%)	36 (20.0%)	14 (21.9%)	18 (21.4%)	32 (21.6%)
Unadjusted Relative Risk (95% CI)	1.09 (0.61, 1.96)					
p-value [1]	0.77					
Unadjusted Odds Ratio (95% CI)	1.12 (0.54, 2.32)					
p-value [1]	0.77					
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.10, 0.13)					
Gastrointestinal disorders						
Constipation	11 (12.8%)	6 (6.4%)	17 (9.4%)	4 (6.3%)	9 (10.7%)	13 (8.8%)
Unadjusted Relative Risk (95% CI)	2.00 (0.77, 5.19)					
p-value [1]	0.15					
Unadjusted Odds Ratio (95% CI)	2.15 (0.76, 6.09)					
p-value [1]	0.15					
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.02, 0.15)					
Gastrointestinal disorders						
Abdominal pain	9 (10.5%)	10 (10.6%)	19 (10.6%)	4 (6.3%)	10 (11.9%)	14 (9.5%)
Unadjusted Relative Risk (95% CI)	0.98 (0.42, 2.31)					
p-value [1]	0.97					
Unadjusted Odds Ratio (95% CI)	0.98 (0.38, 2.54)					
p-value [1]	0.97					
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.09, 0.09)					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019

Table 3.1701: TEAEs with Grade 2 or less by SOC and PT
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)			
				Continuing	Switch		
SOC	MMB	RUX	Total	(MMB->MMB)	(RUX->MMB)	Total	
PT	(N=86)	(N=94)	(N=180)	(N=64)	(N=84)	(N=148)	
General disorders and administration site conditions							
Any Event	36 (41.9%)	45 (47.9%)	81 (45.0%)	28 (43.8%)	31 (36.9%)	59 (39.9%)	
Unadjusted Relative Risk (95% CI)	0.87 (0.63, 1.21)						
p-value [1]	0.42						
Unadjusted Odds Ratio (95% CI)	0.78 (0.43, 1.41)						
p-value [1]	0.42						
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.21, 0.09)						
General disorders and administration site conditions							
Fatigue	13 (15.1%)	11 (11.7%)	24 (13.3%)	6 (9.4%)	11 (13.1%)	17 (11.5%)	
Unadjusted Relative Risk (95% CI)	1.29 (0.61, 2.73)						
p-value [1]	0.50						
Unadjusted Odds Ratio (95% CI)	1.34 (0.57, 3.18)						
p-value [1]	0.50						
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.07, 0.13)						
General disorders and administration site conditions							
Pyrexia	9 (10.5%)	10 (10.6%)	19 (10.6%)	10 (15.6%)	6 (7.1%)	16 (10.8%)	
Unadjusted Relative Risk (95% CI)	0.98 (0.42, 2.31)						
p-value [1]	0.97						
Unadjusted Odds Ratio (95% CI)	0.98 (0.38, 2.54)						
p-value [1]	0.97						
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.09, 0.09)						

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019

Table 3.1701: TEAEs with Grade 2 or less by SOC and PT
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	RUX	Total	(MMB->MMB)	(RUX->MMB)	Total
PT	(N=86)	(N=94)	(N=180)	(N=64)	(N=84)	(N=148)
General disorders and administration site conditions						
Oedema peripheral	6 (7.0%)	8 (8.5%)	14 (7.8%)	8 (12.5%)	3 (3.6%)	11 (7.4%)
Unadjusted Relative Risk (95% CI)	0.82 (0.30, 2.27)					
p-value [1]	0.70					
Unadjusted Odds Ratio (95% CI)	0.81 (0.27, 2.43)					
p-value [1]	0.70					
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.09, 0.06)					
Nervous system disorders						
Any Event	36 (41.9%)	29 (30.9%)	65 (36.1%)	22 (34.4%)	32 (38.1%)	54 (36.5%)
Unadjusted Relative Risk (95% CI)	1.36 (0.92, 2.01)					
p-value [1]	0.13					
Unadjusted Odds Ratio (95% CI)	1.61 (0.87, 2.98)					
p-value [1]	0.13					
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.03, 0.25)					
Nervous system disorders						
Dizziness	15 (17.4%)	10 (10.6%)	25 (13.9%)	6 (9.4%)	14 (16.7%)	20 (13.5%)
Unadjusted Relative Risk (95% CI)	1.64 (0.78, 3.45)					
p-value [1]	0.19					
Unadjusted Odds Ratio (95% CI)	1.77 (0.75, 4.20)					
p-value [1]	0.19					
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.03, 0.17)					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019

Table 3.1701: TEAEs with Grade 2 or less by SOC and PT
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)			
				Continuing	Switch		
SOC	MMB	RUX	Total	(MMB->MMB)	(RUX->MMB)	Total	
PT	(N=86)	(N=94)	(N=180)	(N=64)	(N=84)	(N=148)	
Nervous system disorders							
Headache	10 (11.6%)	15 (16.0%)	25 (13.9%)	2 (3.1%)	3 (3.6%)	5 (3.4%)	
Unadjusted Relative Risk (95% CI)	0.73 (0.35, 1.53)						
p-value [1]	0.40						
Unadjusted Odds Ratio (95% CI)	0.69 (0.29, 1.64)						
p-value [1]	0.40						
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.14, 0.06)						
Nervous system disorders							
Peripheral sensory neuropathy	10 (11.6%)	5 (5.3%)	15 (8.3%)	6 (9.4%)	13 (15.5%)	19 (12.8%)	
Unadjusted Relative Risk (95% CI)	2.19 (0.78, 6.14)						
p-value [1]	0.14						
Unadjusted Odds Ratio (95% CI)	2.34 (0.77, 7.15)						
p-value [1]	0.14						
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.02, 0.14)						
Infections and infestations							
Any Event	32 (37.2%)	44 (46.8%)	76 (42.2%)	28 (43.8%)	44 (52.4%)	72 (48.6%)	
Unadjusted Relative Risk (95% CI)	0.79 (0.56, 1.13)						
p-value [1]	0.20						
Unadjusted Odds Ratio (95% CI)	0.67 (0.37, 1.22)						
p-value [1]	0.19						
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.24, 0.05)						

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.

Table 3.1701: TEAEs with Grade 2 or less by SOC and PT
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	RUX	Total	(MMB->MMB)	(RUX->MMB)	Total
PT	(N=86)	(N=94)	(N=180)	(N=64)	(N=84)	(N=148)
Infections and infestations						
Urinary tract infection	6 (7.0%)	4 (4.3%)	10 (5.6%)	7 (10.9%)	7 (8.3%)	14 (9.5%)
Unadjusted Relative Risk (95% CI)	1.64 (0.48, 5.61)					
p-value [1]	0.43					
Unadjusted Odds Ratio (95% CI)	1.69 (0.46, 6.20)					
p-value [1]	0.43					
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.04, 0.09)					
Infections and infestations						
Upper respiratory tract infection	5 (5.8%)	6 (6.4%)	11 (6.1%)	6 (9.4%)	9 (10.7%)	15 (10.1%)
Unadjusted Relative Risk (95% CI)	0.91 (0.29, 2.88)					
p-value [1]	0.87					
Unadjusted Odds Ratio (95% CI)	0.91 (0.27, 3.08)					
p-value [1]	0.87					
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.08, 0.06)					
Respiratory, thoracic and mediastinal disorders						
Any Event	30 (34.9%)	25 (26.6%)	55 (30.6%)	25 (39.1%)	35 (41.7%)	60 (40.5%)
Unadjusted Relative Risk (95% CI)	1.31 (0.84, 2.04)					
p-value [1]	0.23					
Unadjusted Odds Ratio (95% CI)	1.48 (0.78, 2.80)					
p-value [1]	0.23					
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.05, 0.22)					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019

Table 3.1701: TEAEs with Grade 2 or less by SOC and PT
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	RUX	Total	(MMB->MMB)	(RUX->MMB)	Total
PT	(N=86)	(N=94)	(N=180)	(N=64)	(N=84)	(N=148)
Respiratory, thoracic and mediastinal disorders						
Cough	12 (14.0%)	9 (9.6%)	21 (11.7%)	12 (18.8%)	15 (17.9%)	27 (18.2%)
Unadjusted Relative Risk (95% CI)	1.46 (0.65, 3.29)					
p-value [1]	0.36					
Unadjusted Odds Ratio (95% CI)	1.53 (0.61, 3.84)					
p-value [1]	0.36					
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.05, 0.14)					
Respiratory, thoracic and mediastinal disorders						
Dyspnoea	11 (12.8%)	7 (7.4%)	18 (10.0%)	6 (9.4%)	5 (6.0%)	11 (7.4%)
Unadjusted Relative Risk (95% CI)	1.72 (0.70, 4.23)					
p-value [1]	0.24					
Unadjusted Odds Ratio (95% CI)	1.82 (0.67, 4.94)					
p-value [1]	0.24					
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.03, 0.14)					
Blood and lymphatic system disorders						
Any Event	26 (30.2%)	45 (47.9%)	71 (39.4%)	15 (23.4%)	27 (32.1%)	42 (28.4%)
Unadjusted Relative Risk (95% CI)	0.63 (0.43, 0.93)					
p-value [1]	0.019					
Unadjusted Odds Ratio (95% CI)	0.47 (0.26, 0.87)					
p-value [1]	0.016					
Unadjusted Absolute Risk Difference (95% CI)	-0.18 (-0.32, -0.04)					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019

Table 3.1701: TEAEs with Grade 2 or less by SOC and PT
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	RUX	Total	(MMB->MMB)	(RUX->MMB)	Total
PT	(N=86)	(N=94)	(N=180)	(N=64)	(N=84)	(N=148)
Blood and lymphatic system disorders						
Thrombocytopenia	16 (18.6%)	28 (29.8%)	44 (24.4%)	10 (15.6%)	11 (13.1%)	21 (14.2%)
Unadjusted Relative Risk (95% CI)	0.62 (0.36, 1.07)					
p-value [1]	0.088					
Unadjusted Odds Ratio (95% CI)	0.54 (0.27, 1.09)					
p-value [1]	0.083					
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.24, 0.01)					
Blood and lymphatic system disorders						
Anaemia	8 (9.3%)	21 (22.3%)	29 (16.1%)	7 (10.9%)	10 (11.9%)	17 (11.5%)
Unadjusted Relative Risk (95% CI)	0.42 (0.19, 0.89)					
p-value [1]	0.024					
Unadjusted Odds Ratio (95% CI)	0.36 (0.15, 0.85)					
p-value [1]	0.021					
Unadjusted Absolute Risk Difference (95% CI)	-0.13 (-0.23, -0.03)					
Metabolism and nutrition disorders						
Any Event	21 (24.4%)	17 (18.1%)	38 (21.1%)	23 (35.9%)	33 (39.3%)	56 (37.8%)
Unadjusted Relative Risk (95% CI)	1.35 (0.76, 2.38)					
p-value [1]	0.30					
Unadjusted Odds Ratio (95% CI)	1.46 (0.71, 3.01)					
p-value [1]	0.30					
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.06, 0.18)					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019

Table 3.1701: TEAEs with Grade 2 or less by SOC and PT
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
SOC PT	MMB (N=86)	RUX (N=94)	Total (N=180)	(MMB->MMB) (N=64)	(RUX->MMB) (N=84)	Total (N=148)
Metabolism and nutrition disorders						
Vitamin B1 deficiency	5 (5.8%)	6 (6.4%)	11 (6.1%)	7 (10.9%)	8 (9.5%)	15 (10.1%)
Unadjusted Relative Risk (95% CI)	0.91 (0.29, 2.88)					
p-value [1]	0.87					
Unadjusted Odds Ratio (95% CI)	0.91 (0.27, 3.08)					
p-value [1]	0.87					
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.08, 0.06)					
Musculoskeletal and connective tissue disorders						
Any Event	21 (24.4%)	23 (24.5%)	44 (24.4%)	16 (25.0%)	29 (34.5%)	45 (30.4%)
Unadjusted Relative Risk (95% CI)	1.00 (0.60, 1.67)					
p-value [1]	>0.99					
Unadjusted Odds Ratio (95% CI)	1.00 (0.50, 1.97)					
p-value [1]	>0.99					
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.13, 0.13)					
Musculoskeletal and connective tissue disorders						
Pain in extremity	9 (10.5%)	5 (5.3%)	14 (7.8%)	7 (10.9%)	6 (7.1%)	13 (8.8%)
Unadjusted Relative Risk (95% CI)	1.97 (0.69, 5.64)					
p-value [1]	0.21					
Unadjusted Odds Ratio (95% CI)	2.08 (0.67, 6.47)					
p-value [1]	0.21					
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.03, 0.13)					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019

Table 3.1701: TEAEs with Grade 2 or less by SOC and PT
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	RUX	Total	(MMB->MMB)	(RUX->MMB)	Total
PT	(N=86)	(N=94)	(N=180)	(N=64)	(N=84)	(N=148)
Musculoskeletal and connective tissue disorders						
Back pain	5 (5.8%)	2 (2.1%)	7 (3.9%)	4 (6.3%)	11 (13.1%)	15 (10.1%)
Unadjusted Relative Risk (95% CI)	2.73 (0.54, 13.72)					
p-value [1]	0.22					
Unadjusted Odds Ratio (95% CI)	2.84 (0.54, 15.04)					
p-value [1]	0.22					
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.02, 0.09)					
Skin and subcutaneous tissue disorders						
Any Event	20 (23.3%)	14 (14.9%)	34 (18.9%)	24 (37.5%)	24 (28.6%)	48 (32.4%)
Unadjusted Relative Risk (95% CI)	1.56 (0.84, 2.89)					
p-value [1]	0.16					
Unadjusted Odds Ratio (95% CI)	1.73 (0.81, 3.69)					
p-value [1]	0.16					
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.03, 0.20)					
Skin and subcutaneous tissue disorders						
Rash	5 (5.8%)	2 (2.1%)	7 (3.9%)	7 (10.9%)	5 (6.0%)	12 (8.1%)
Unadjusted Relative Risk (95% CI)	2.73 (0.54, 13.72)					
p-value [1]	0.22					
Unadjusted Odds Ratio (95% CI)	2.84 (0.54, 15.04)					
p-value [1]	0.22					
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.02, 0.09)					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019

Table 3.1701: TEAEs with Grade 2 or less by SOC and PT
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	RUX	Total	(MMB->MMB)	(RUX->MMB)	Total
PT	(N=86)	(N=94)	(N=180)	(N=64)	(N=84)	(N=148)
Skin and subcutaneous tissue disorders						
Night sweats	4 (4.7%)	1 (1.1%)	5 (2.8%)	7 (10.9%)	4 (4.8%)	11 (7.4%)
Unadjusted Relative Risk (95% CI)	4.37 (0.50, 38.36)					
p-value [1]	0.18					
Unadjusted Odds Ratio (95% CI)	4.54 (0.50, 41.41)					
p-value [1]	0.18					
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.01, 0.08)					
Investigations						
Any Event	19 (22.1%)	19 (20.2%)	38 (21.1%)	14 (21.9%)	18 (21.4%)	32 (21.6%)
Unadjusted Relative Risk (95% CI)	1.09 (0.62, 1.92)					
p-value [1]	0.76					
Unadjusted Odds Ratio (95% CI)	1.12 (0.55, 2.29)					
p-value [1]	0.76					
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.10, 0.14)					
Vascular disorders						
Any Event	16 (18.6%)	5 (5.3%)	21 (11.7%)	12 (18.8%)	14 (16.7%)	26 (17.6%)
Unadjusted Relative Risk (95% CI)	3.50 (1.34, 9.14)					
p-value [1]	0.011					
Unadjusted Odds Ratio (95% CI)	4.07 (1.42, 11.65)					
p-value [1]	0.009					
Unadjusted Absolute Risk Difference (95% CI)	0.13 (0.04, 0.23)					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019

Table 3.1701: TEAEs with Grade 2 or less by SOC and PT
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
SOC PT	MMB (N=86)	RUX (N=94)	Total (N=180)	(MMB->MMB) (N=64)	(RUX->MMB) (N=84)	Total (N=148)
Vascular disorders						
Hypotension	10 (11.6%)	0	10 (5.6%)	1 (1.6%)	3 (3.6%)	4 (2.7%)
Unadjusted Relative Risk (95% CI)	22.93 (1.36, 385.53)					
p-value [1]	0.030					
Unadjusted Odds Ratio (95% CI)	25.94 (1.50, 449.84)					
p-value [1]	0.025					
Unadjusted Absolute Risk Difference (95% CI)	0.12 (0.05, 0.19)					
Injury, poisoning and procedural complications						
Any Event	11 (12.8%)	14 (14.9%)	25 (13.9%)	13 (20.3%)	10 (11.9%)	23 (15.5%)
Unadjusted Relative Risk (95% CI)	0.86 (0.41, 1.79)					
p-value [1]	0.68					
Unadjusted Odds Ratio (95% CI)	0.84 (0.36, 1.96)					
p-value [1]	0.68					
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.12, 0.08)					
Eye disorders						
Any Event	10 (11.6%)	7 (7.4%)	17 (9.4%)	13 (20.3%)	8 (9.5%)	21 (14.2%)
Unadjusted Relative Risk (95% CI)	1.56 (0.62, 3.92)					
p-value [1]	0.34					
Unadjusted Odds Ratio (95% CI)	1.64 (0.59, 4.51)					
p-value [1]	0.34					
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.04, 0.13)					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019

Table 3.1701: TEAEs with Grade 2 or less by SOC and PT
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
SOC PT	MMB (N=86)	RUX (N=94)	Total (N=180)	(MMB->MMB) (N=64)	(RUX->MMB) (N=84)	Total (N=148)
Renal and urinary disorders						
Any Event	10 (11.6%)	7 (7.4%)	17 (9.4%)	13 (20.3%)	9 (10.7%)	22 (14.9%)
Unadjusted Relative Risk (95% CI)	1.56 (0.62, 3.92)					
p-value [1]	0.34					
Unadjusted Odds Ratio (95% CI)	1.64 (0.59, 4.51)					
p-value [1]	0.34					
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.04, 0.13)					
Cardiac disorders						
Any Event	9 (10.5%)	6 (6.4%)	15 (8.3%)	10 (15.6%)	5 (6.0%)	15 (10.1%)
Unadjusted Relative Risk (95% CI)	1.64 (0.61, 4.42)					
p-value [1]	0.33					
Unadjusted Odds Ratio (95% CI)	1.71 (0.58, 5.03)					
p-value [1]	0.33					
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.04, 0.12)					
Psychiatric disorders						
Any Event	8 (9.3%)	6 (6.4%)	14 (7.8%)	13 (20.3%)	9 (10.7%)	22 (14.9%)
Unadjusted Relative Risk (95% CI)	1.46 (0.53, 4.03)					
p-value [1]	0.47					
Unadjusted Odds Ratio (95% CI)	1.50 (0.50, 4.53)					
p-value [1]	0.47					
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.05, 0.11)					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019

Table 3.1701: TEAEs with Grade 2 or less by SOC and PT
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	RUX	Total	(MMB->MMB)	(RUX->MMB)	Total
PT	(N=86)	(N=94)	(N=180)	(N=64)	(N=84)	(N=148)
Psychiatric disorders						
Insomnia	1 (1.2%)	2 (2.1%)	3 (1.7%)	7 (10.9%)	4 (4.8%)	11 (7.4%)
Unadjusted Relative Risk (95% CI)	0.55 (0.05, 5.92)					
p-value [1]	0.62					
Unadjusted Odds Ratio (95% CI)	0.54 (0.05, 6.08)					
p-value [1]	0.62					
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.05, 0.03)					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019

1.10.4 SUE

GSK Oncology
Study GS-US-352-0101

Table 3.1901: Serious TEAEs by SOC and PT
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)			
				Continuing	Switch		
SOC	MMB	RUX	Total	(MMB->MMB)	(RUX->MMB)	Total	
PT	(N=86)	(N=94)	(N=180)	(N=64)	(N=84)	(N=148)	
Any Serious TEAE							
Number of Subjects With Any Event	26 (30.2%)	23 (24.5%)	49 (27.2%)	35 (54.7%)	38 (45.2%)	73 (49.3%)	
Unadjusted Relative Risk (95% CI)	1.24 (0.77, 1.99)						
p-value [1]	0.39						
Unadjusted Odds Ratio (95% CI)	1.34 (0.69, 2.58)						
p-value [1]	0.39						
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.07, 0.19)						
Infections and infestations							
Any Event	8 (9.3%)	6 (6.4%)	14 (7.8%)	18 (28.1%)	18 (21.4%)	36 (24.3%)	
Unadjusted Relative Risk (95% CI)	1.46 (0.53, 4.03)						
p-value [1]	0.47						
Unadjusted Odds Ratio (95% CI)	1.50 (0.50, 4.53)						
p-value [1]	0.47						
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.05, 0.11)						
Infections and infestations							
Pneumonia	3 (3.5%)	3 (3.2%)	6 (3.3%)	10 (15.6%)	6 (7.1%)	16 (10.8%)	
Unadjusted Relative Risk (95% CI)	1.09 (0.23, 5.27)						
p-value [1]	0.91						
Unadjusted Odds Ratio (95% CI)	1.10 (0.22, 5.58)						
p-value [1]	0.91						
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.05, 0.06)						

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-ser-gba.sas V.03.05 Output file: t-ae-socpt-ser-gba.pdf 24AUG2023:12:47

Table 3.1901: Serious TEAEs by SOC and PT
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	RUX	Total	(MMB->MMB)	(RUX->MMB)	Total
PT	(N=86)	(N=94)	(N=180)	(N=64)	(N=84)	(N=148)
Cardiac disorders						
Any Event	6 (7.0%)	4 (4.3%)	10 (5.6%)	5 (7.8%)	6 (7.1%)	11 (7.4%)
Unadjusted Relative Risk (95% CI)	1.64 (0.48, 5.61)					
p-value [1]	0.43					
Unadjusted Odds Ratio (95% CI)	1.69 (0.46, 6.20)					
p-value [1]	0.43					
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.04, 0.09)					
Gastrointestinal disorders						
Any Event	4 (4.7%)	4 (4.3%)	8 (4.4%)	3 (4.7%)	7 (8.3%)	10 (6.8%)
Unadjusted Relative Risk (95% CI)	1.09 (0.28, 4.24)					
p-value [1]	0.90					
Unadjusted Odds Ratio (95% CI)	1.10 (0.27, 4.53)					
p-value [1]	0.90					
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.06, 0.06)					
Renal and urinary disorders						
Any Event	4 (4.7%)	2 (2.1%)	6 (3.3%)	6 (9.4%)	6 (7.1%)	12 (8.1%)
Unadjusted Relative Risk (95% CI)	2.19 (0.41, 11.64)					
p-value [1]	0.36					
Unadjusted Odds Ratio (95% CI)	2.24 (0.40, 12.57)					
p-value [1]	0.36					
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.03, 0.08)					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.

Table 3.1901: Serious TEAEs by SOC and PT
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)			
				Continuing	Switch		
SOC	MMB	RUX	Total	(MMB->MMB)	(RUX->MMB)	Total	
PT	(N=86)	(N=94)	(N=180)	(N=64)	(N=84)	(N=148)	
Respiratory, thoracic and mediastinal disorders							
Any Event	4 (4.7%)	1 (1.1%)	5 (2.8%)	5 (7.8%)	7 (8.3%)	12 (8.1%)	
Unadjusted Relative Risk (95% CI)	4.37 (0.50, 38.36)						
p-value [1]	0.18						
Unadjusted Odds Ratio (95% CI)	4.54 (0.50, 41.41)						
p-value [1]	0.18						
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.01, 0.08)						
Blood and lymphatic system disorders							
Any Event	3 (3.5%)	6 (6.4%)	9 (5.0%)	5 (7.8%)	5 (6.0%)	10 (6.8%)	
Unadjusted Relative Risk (95% CI)	0.55 (0.14, 2.12)						
p-value [1]	0.38						
Unadjusted Odds Ratio (95% CI)	0.53 (0.13, 2.19)						
p-value [1]	0.38						
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.09, 0.03)						
Blood and lymphatic system disorders							
Anaemia	3 (3.5%)	5 (5.3%)	8 (4.4%)	5 (7.8%)	2 (2.4%)	7 (4.7%)	
Unadjusted Relative Risk (95% CI)	0.66 (0.16, 2.66)						
p-value [1]	0.56						
Unadjusted Odds Ratio (95% CI)	0.64 (0.15, 2.78)						
p-value [1]	0.55						
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.08, 0.04)						

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.

Table 3.1901: Serious TEAEs by SOC and PT
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)			
				Continuing	Switch		
SOC PT	MMB (N=86)	RUX (N=94)	Total (N=180)	(MMB->MMB) (N=64)	(RUX->MMB) (N=84)	Total (N=148)	
General disorders and administration site conditions							
Any Event	3 (3.5%)	5 (5.3%)	8 (4.4%)	4 (6.3%)	3 (3.6%)	7 (4.7%)	
Unadjusted Relative Risk (95% CI)	0.66 (0.16, 2.66)						
p-value [1]	0.56						
Unadjusted Odds Ratio (95% CI)	0.64 (0.15, 2.78)						
p-value [1]	0.55						
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.08, 0.04)						
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Any Event	2 (2.3%)	1 (1.1%)	3 (1.7%)	3 (4.7%)	6 (7.1%)	9 (6.1%)	
Unadjusted Relative Risk (95% CI)	2.19 (0.20, 23.68)						
p-value [1]	0.52						
Unadjusted Odds Ratio (95% CI)	2.21 (0.20, 24.87)						
p-value [1]	0.52						
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.03, 0.05)						
Nervous system disorders							
Any Event	1 (1.2%)	1 (1.1%)	2 (1.1%)	7 (10.9%)	2 (2.4%)	9 (6.1%)	
Unadjusted Relative Risk (95% CI)	1.09 (0.07, 17.21)						
p-value [1]	0.95						
Unadjusted Odds Ratio (95% CI)	1.09 (0.07, 17.77)						
p-value [1]	0.95						
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.03, 0.03)						

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019

1.10.5 Therapieabbrüche

GSK Oncology
Study GS-US-352-0101
Table 3.0501: TEAE Leading to Premature Discontinuation of Study Drug (MMB\Ruxolitinib\Placebo) by SOC and PT
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	DB Phase			DB Phase		
	MMB\MMB Matched Placebo			RUX\RUX Matched Placebo		
	MMB (N=86)	RUX (N=94)	Total (N=180)	MMB (N=86)	RUX (N=94)	Total (N=180)
Number of Subjects with Any Treatment-Emergent AE Leading to Discontinuation of Study Drug	17 (19.8%)	5 (5.3%)	22 (12.2%)	17 (19.8%)	5 (5.3%)	22 (12.2%)
Number of Subjects with Treatment-Emergent AE Leading to Discontinuation of Study Drug, By System Organ Class And Preferred Term						
Blood and lymphatic system disorders	3 (3.5%)	3 (3.2%)	6 (3.3%)	3 (3.5%)	3 (3.2%)	6 (3.3%)
Thrombocytopenia	2 (2.3%)	3 (3.2%)	5 (2.8%)	2 (2.3%)	3 (3.2%)	5 (2.8%)
Splenomegaly	1 (1.2%)	0	1 (0.6%)	1 (1.2%)	0	1 (0.6%)
Leukocytosis	0	0	0	0	0	0
Neutropenia	0	0	0	0	0	0
Gastrointestinal disorders	3 (3.5%)	1 (1.1%)	4 (2.2%)	2 (2.3%)	1 (1.1%)	3 (1.7%)
Abdominal pain	1 (1.2%)	0	1 (0.6%)	0	0	0
Diarrhoea	1 (1.2%)	0	1 (0.6%)	1 (1.2%)	0	1 (0.6%)
Nausea	1 (1.2%)	0	1 (0.6%)	1 (1.2%)	0	1 (0.6%)
Vomiting	1 (1.2%)	0	1 (0.6%)	1 (1.2%)	0	1 (0.6%)
Dry mouth	0	0	0	0	0	0
Retching	0	0	0	0	0	0
Subileus	0	1 (1.1%)	1 (0.6%)	0	1 (1.1%)	1 (0.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs and then PTs within an SOC were presented by descending order of the frequencies under "MMB" column of "MMB\MMB Placebo".
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-teae-dc-drug-db_csr.sas V.03.05 Output file: t-teae-dc-drug-db.pdf 29AUG2023: 9:40

Table 3.0501: TEAE Leading to Premature Discontinuation of Study Drug (MMB\Ruxolitinib\Placebo) by SOC and PT
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	OL Phase (Week 24 - Week 48) OL MMB Continuing (MMB->MMB) (N=64)	OL Phase (Week 24 - Week 48) OL MMB Switch (RUX->MMB) (N=84)	OL Phase (Week 24 - Week 48) OL MMB Total (N=148)
Number of Subjects with Any Treatment-Emergent AE Leading to Discontinuation of Study Drug	7 (10.9%)	9 (10.7%)	16 (10.8%)
Number of Subjects with Treatment-Emergent AE Leading to Discontinuation of Study Drug, By System Organ Class And Preferred Term			
Blood and lymphatic system disorders	1 (1.6%)	2 (2.4%)	3 (2.0%)
Thrombocytopenia	0	1 (1.2%)	1 (0.7%)
Splenomegaly	1 (1.6%)	0	1 (0.7%)
Leukocytosis	1 (1.6%)	0	1 (0.7%)
Neutropenia	0	1 (1.2%)	1 (0.7%)
Gastrointestinal disorders	1 (1.6%)	1 (1.2%)	2 (1.4%)
Abdominal pain	0	0	0
Diarrhoea	0	1 (1.2%)	1 (0.7%)
Nausea	1 (1.6%)	0	1 (0.7%)
Vomiting	0	0	0
Dry mouth	0	1 (1.2%)	1 (0.7%)
Retching	0	1 (1.2%)	1 (0.7%)
Subileus	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs and then PTs within an SOC were presented by descending order of the frequencies under "MMB" column of "MMB\MMB Placebo".
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0501: TEAE Leading to Premature Discontinuation of Study Drug (MMB\Ruxolitinib\Placebo) by SOC and PT
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	DB Phase			DB Phase		
	MMB\MMB Matched Placebo			RUX\RUX Matched Placebo		
	MMB (N=86)	RUX (N=94)	Total (N=180)	MMB (N=86)	RUX (N=94)	Total (N=180)
Number of Subjects with Any Treatment-Emergent AE Leading to Discontinuation of Study Drug	17 (19.8%)	5 (5.3%)	22 (12.2%)	17 (19.8%)	5 (5.3%)	22 (12.2%)
Number of Subjects with Treatment-Emergent AE Leading to Discontinuation of Study Drug, By System Organ Class And Preferred Term						
General disorders and administration site conditions	3 (3.5%)	0	3 (1.7%)	3 (3.5%)	0	3 (1.7%)
Malaise	2 (2.3%)	0	2 (1.1%)	2 (2.3%)	0	2 (1.1%)
Sudden death	1 (1.2%)	0	1 (0.6%)	1 (1.2%)	0	1 (0.6%)
Impaired healing	0	0	0	0	0	0
Vascular disorders	3 (3.5%)	0	3 (1.7%)	3 (3.5%)	0	3 (1.7%)
Hypotension	2 (2.3%)	0	2 (1.1%)	2 (2.3%)	0	2 (1.1%)
Flushing	1 (1.2%)	0	1 (0.6%)	1 (1.2%)	0	1 (0.6%)
Infections and infestations	2 (2.3%)	1 (1.1%)	3 (1.7%)	2 (2.3%)	1 (1.1%)	3 (1.7%)
Escherichia sepsis	1 (1.2%)	0	1 (0.6%)	1 (1.2%)	0	1 (0.6%)
Pneumonia bacterial	1 (1.2%)	0	1 (0.6%)	1 (1.2%)	0	1 (0.6%)
Pneumonia	0	1 (1.1%)	1 (0.6%)	0	1 (1.1%)	1 (0.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs and then PTs within an SOC were presented by descending order of the frequencies under "MMB" column of "MMB\MMB Placebo".
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0501: TEAE Leading to Premature Discontinuation of Study Drug (MMB\Ruxolitinib\Placebo) by SOC and PT
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	OL Phase (Week 24 - Week 48) OL MMB Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)
Number of Subjects with Any Treatment-Emergent AE Leading to Discontinuation of Study Drug	7 (10.9%)	9 (10.7%)	16 (10.8%)
Number of Subjects with Treatment-Emergent AE Leading to Discontinuation of Study Drug, By System Organ Class And Preferred Term			
General disorders and administration site conditions	0	2 (2.4%)	2 (1.4%)
Malaise	0	1 (1.2%)	1 (0.7%)
Sudden death	0	0	0
Impaired healing	0	1 (1.2%)	1 (0.7%)
Vascular disorders	0	0	0
Hypotension	0	0	0
Flushing	0	0	0
Infections and infestations	1 (1.6%)	0	1 (0.7%)
Escherichia sepsis	0	0	0
Pneumonia bacterial	0	0	0
Pneumonia	1 (1.6%)	0	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs and then PTs within an SOC were presented by descending order of the frequencies under "MMB" column of "MMB\MMB Placebo".
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0501: TEAE Leading to Premature Discontinuation of Study Drug (MMB\Ruxolitinib\Placebo) by SOC and PT
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	DB Phase			DB Phase		
	MMB\MMB Matched Placebo			RUX\RUX Matched Placebo		
	MMB (N=86)	RUX (N=94)	Total (N=180)	MMB (N=86)	RUX (N=94)	Total (N=180)
Number of Subjects with Any Treatment-Emergent AE Leading to Discontinuation of Study Drug	17 (19.8%)	5 (5.3%)	22 (12.2%)	17 (19.8%)	5 (5.3%)	22 (12.2%)
Number of Subjects with Treatment-Emergent AE Leading to Discontinuation of Study Drug, By System Organ Class And Preferred Term						
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (2.3%)	1 (1.1%)	3 (1.7%)	2 (2.3%)	1 (1.1%)	3 (1.7%)
Ovarian clear cell carcinoma	1 (1.2%)	0	1 (0.6%)	1 (1.2%)	0	1 (0.6%)
Splenic marginal zone lymphoma	1 (1.2%)	0	1 (0.6%)	1 (1.2%)	0	1 (0.6%)
Uterine cancer	1 (1.2%)	0	1 (0.6%)	1 (1.2%)	0	1 (0.6%)
Leukoerythroblastosis	0	0	0	0	0	0
Mantle cell lymphoma recurrent	0	1 (1.1%)	1 (0.6%)	0	1 (1.1%)	1 (0.6%)
Rectal cancer	0	0	0	0	0	0
Nervous system disorders	2 (2.3%)	0	2 (1.1%)	2 (2.3%)	0	2 (1.1%)
Dizziness	2 (2.3%)	0	2 (1.1%)	2 (2.3%)	0	2 (1.1%)
Paraesthesia	1 (1.2%)	0	1 (0.6%)	1 (1.2%)	0	1 (0.6%)
Cerebrovascular accident	0	0	0	0	0	0
Peripheral sensorimotor neuropathy	0	0	0	0	0	0
Peripheral sensory neuropathy	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs and then PTs within an SOC were presented by descending order of the frequencies under "MMB" column of "MMB\MMB Placebo".
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0501: TEAE Leading to Premature Discontinuation of Study Drug (MMB\Ruxolitinib\Placebo) by SOC and PT
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	OL Phase (Week 24 - Week 48)		
	OL MMB		
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)
Number of Subjects with Any Treatment-Emergent AE Leading to Discontinuation of Study Drug	7 (10.9%)	9 (10.7%)	16 (10.8%)
Number of Subjects with Treatment-Emergent AE Leading to Discontinuation of Study Drug, By System Organ Class And Preferred Term			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (3.1%)	0	2 (1.4%)
Ovarian clear cell carcinoma	0	0	0
Splenic marginal zone lymphoma	0	0	0
Uterine cancer	0	0	0
Leukoerythroblastosis	1 (1.6%)	0	1 (0.7%)
Mantle cell lymphoma recurrent	0	0	0
Rectal cancer	1 (1.6%)	0	1 (0.7%)
Nervous system disorders	2 (3.1%)	2 (2.4%)	4 (2.7%)
Dizziness	0	0	0
Paraesthesia	0	0	0
Cerebrovascular accident	1 (1.6%)	0	1 (0.7%)
Peripheral sensorimotor neuropathy	1 (1.6%)	0	1 (0.7%)
Peripheral sensory neuropathy	0	2 (2.4%)	2 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs and then PTs within an SOC were presented by descending order of the frequencies under "MMB" column of "MMB\MMB Placebo".
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0501: TEAE Leading to Premature Discontinuation of Study Drug (MMB\Ruxolitinib\Placebo) by SOC and PT
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	DB Phase			DB Phase		
	MMB\MMB Matched Placebo			RUX\RUX Matched Placebo		
	MMB (N=86)	RUX (N=94)	Total (N=180)	MMB (N=86)	RUX (N=94)	Total (N=180)
Number of Subjects with Any Treatment-Emergent AE Leading to Discontinuation of Study Drug	17 (19.8%)	5 (5.3%)	22 (12.2%)	17 (19.8%)	5 (5.3%)	22 (12.2%)
Number of Subjects with Treatment-Emergent AE Leading to Discontinuation of Study Drug, By System Organ Class And Preferred Term						
Cardiac disorders	1 (1.2%)	0	1 (0.6%)	1 (1.2%)	0	1 (0.6%)
Cardiac failure	1 (1.2%)	0	1 (0.6%)	1 (1.2%)	0	1 (0.6%)
Atrial fibrillation	0	0	0	0	0	0
Investigations	1 (1.2%)	0	1 (0.6%)	2 (2.3%)	0	2 (1.1%)
Electrocardiogram QT prolonged	1 (1.2%)	0	1 (0.6%)	1 (1.2%)	0	1 (0.6%)
Alanine aminotransferase increased	0	0	0	1 (1.2%)	0	1 (0.6%)
Aspartate aminotransferase increased	0	0	0	1 (1.2%)	0	1 (0.6%)
Blood alkaline phosphatase increased	0	0	0	1 (1.2%)	0	1 (0.6%)
Blood creatinine increased	0	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders	1 (1.2%)	0	1 (0.6%)	1 (1.2%)	0	1 (0.6%)
Hypoxia	1 (1.2%)	0	1 (0.6%)	1 (1.2%)	0	1 (0.6%)
Epistaxis	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs and then PTs within an SOC were presented by descending order of the frequencies under "MMB" column of "MMB\MMB Placebo".
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0501: TEAE Leading to Premature Discontinuation of Study Drug (MMB\Ruxolitinib\Placebo) by SOC and PT
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	OL Phase (Week 24 - Week 48) OL MMB Continuing (MMB->MMB) (N=64)	OL Phase (Week 24 - Week 48) OL MMB Switch (RUX->MMB) (N=84)	OL Phase (Week 24 - Week 48) OL MMB Total (N=148)
Number of Subjects with Any Treatment-Emergent AE Leading to Discontinuation of Study Drug	7 (10.9%)	9 (10.7%)	16 (10.8%)
Number of Subjects with Treatment-Emergent AE Leading to Discontinuation of Study Drug, By System Organ Class And Preferred Term			
Cardiac disorders	0	1 (1.2%)	1 (0.7%)
Cardiac failure	0	0	0
Atrial fibrillation	0	1 (1.2%)	1 (0.7%)
Investigations	1 (1.6%)	0	1 (0.7%)
Electrocardiogram QT prolonged	0	0	0
Alanine aminotransferase increased	0	0	0
Aspartate aminotransferase increased	0	0	0
Blood alkaline phosphatase increased	0	0	0
Blood creatinine increased	1 (1.6%)	0	1 (0.7%)
Respiratory, thoracic and mediastinal disorders	1 (1.6%)	0	1 (0.7%)
Hypoxia	0	0	0
Epistaxis	1 (1.6%)	0	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs and then PTs within an SOC were presented by descending order of the frequencies under "MMB" column of "MMB\MMB Placebo".
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-teae-dc-drug-db_csr.sas V.03.05 Output file: t-teae-dc-drug-db.pdf 29AUG2023: 9:40

Table 3.0501: TEAE Leading to Premature Discontinuation of Study Drug (MMB\Ruxolitinib\Placebo) by SOC and PT
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	DB Phase			DB Phase		
	MMB\MMB Matched Placebo			RUX\RUX Matched Placebo		
	MMB (N=86)	RUX (N=94)	Total (N=180)	MMB (N=86)	RUX (N=94)	Total (N=180)
Number of Subjects with Any Treatment-Emergent AE Leading to Discontinuation of Study Drug	17 (19.8%)	5 (5.3%)	22 (12.2%)	17 (19.8%)	5 (5.3%)	22 (12.2%)
Number of Subjects with Treatment-Emergent AE Leading to Discontinuation of Study Drug, By System Organ Class And Preferred Term						
Eye disorders	0	0	0	0	0	0
Eye haemorrhage	0	0	0	0	0	0
Eye pain	0	0	0	0	0	0
Vision blurred	0	0	0	0	0	0
Renal and urinary disorders	0	1 (1.1%)	1 (0.6%)	0	1 (1.1%)	1 (0.6%)
Acute kidney injury	0	1 (1.1%)	1 (0.6%)	0	1 (1.1%)	1 (0.6%)
Haematuria	0	1 (1.1%)	1 (0.6%)	0	1 (1.1%)	1 (0.6%)
Skin and subcutaneous tissue disorders	0	0	0	0	0	0
Dermatitis allergic	0	0	0	0	0	0
Drug eruption	0	0	0	0	0	0
Hyperhidrosis	0	0	0	0	0	0
Toxic skin eruption	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs and then PTs within an SOC were presented by descending order of the frequencies under "MMB" column of "MMB\MMB Placebo".
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0501: TEAE Leading to Premature Discontinuation of Study Drug (MMB\Ruxolitinib\Placebo) by SOC and PT
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	OL Phase (Week 24 - Week 48)		
	OL MMB		
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)
Number of Subjects with Any Treatment-Emergent AE Leading to Discontinuation of Study Drug	7 (10.9%)	9 (10.7%)	16 (10.8%)
Number of Subjects with Treatment-Emergent AE Leading to Discontinuation of Study Drug, By System Organ Class And Preferred Term			
Eye disorders	1 (1.6%)	0	1 (0.7%)
Eye haemorrhage	1 (1.6%)	0	1 (0.7%)
Eye pain	1 (1.6%)	0	1 (0.7%)
Vision blurred	1 (1.6%)	0	1 (0.7%)
Renal and urinary disorders	1 (1.6%)	0	1 (0.7%)
Acute kidney injury	1 (1.6%)	0	1 (0.7%)
Haematuria	0	0	0
Skin and subcutaneous tissue disorders	1 (1.6%)	2 (2.4%)	3 (2.0%)
Dermatitis allergic	1 (1.6%)	0	1 (0.7%)
Drug eruption	0	1 (1.2%)	1 (0.7%)
Hyperhidrosis	0	1 (1.2%)	1 (0.7%)
Toxic skin eruption	1 (1.6%)	0	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs and then PTs within an SOC were presented by descending order of the frequencies under "MMB" column of "MMB\MMB Placebo".
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.1004: TEAE Leading to Premature Discontinuation of Study Drug (MMB) by SOC, PT, and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	OL Phase (Week 24 Onward)			Overall Exposed to MMB
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE Leading to Discontinuation of Study Drug	21 (32.8%)	22 (26.2%)	43 (29.1%)	61 (35.9%)
Grade 1	0	2 (2.4%)	2 (1.4%)	7 (4.1%)
Grade 2	2 (3.1%)	6 (7.1%)	8 (5.4%)	9 (5.3%)
Grade 3	13 (20.3%)	13 (15.5%)	26 (17.6%)	32 (18.8%)
Grade 4	5 (7.8%)	0	5 (3.4%)	10 (5.9%)
Grade 5	1 (1.6%)	1 (1.2%)	2 (1.4%)	3 (1.8%)
Number of Subjects with Treatment-Emergent AE Leading to Discontinuation of Study Drug, By System Organ Class, Preferred Term And Standard Toxicity Grade				
Blood and lymphatic system disorders	3 (4.7%)	5 (6.0%)	8 (5.4%)	11 (6.5%)
Grade 1	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Grade 2	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Grade 3	2 (3.1%)	3 (3.6%)	5 (3.4%)	7 (4.1%)
Grade 4	1 (1.6%)	0	1 (0.7%)	2 (1.2%)
Thrombocytopenia	1 (1.6%)	2 (2.4%)	3 (2.0%)	5 (2.9%)
Grade 3	1 (1.6%)	2 (2.4%)	3 (2.0%)	4 (2.4%)
Grade 4	0	0	0	1 (0.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs and then PTs within an SOC were presented by descending order of the frequencies under the last column.
The most severe AE within a PT was counted for each subject.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-tox.sas V.03.05 Output file: t-teae-dc-drug-ol.pdf 29AUG2023: 9:44

Table 3.1004: TEAE Leading to Premature Discontinuation of Study Drug (MMB) by SOC, PT, and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	OL Phase (Week 24 Onward)			Overall Exposed to MMB
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE Leading to Discontinuation of Study Drug	21 (32.8%)	22 (26.2%)	43 (29.1%)	61 (35.9%)
Number of Subjects with Treatment-Emergent AE Leading to Discontinuation of Study Drug, By System Organ Class, Preferred Term And Standard Toxicity Grade				
Blood and lymphatic system disorders (cont)				
Leukocytosis	1 (1.6%)	1 (1.2%)	2 (1.4%)	2 (1.2%)
Grade 2	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Grade 3	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Splenomegaly	1 (1.6%)	0	1 (0.7%)	2 (1.2%)
Grade 3	1 (1.6%)	0	1 (0.7%)	2 (1.2%)
Anaemia	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Grade 3	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Haemolytic anaemia	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Grade 4	1 (1.6%)	0	1 (0.7%)	1 (0.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs and then PTs within an SOC were presented by descending order of the frequencies under the last column.
The most severe AE within a PT was counted for each subject.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.1004: TEAE Leading to Premature Discontinuation of Study Drug (MMB) by SOC, PT, and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	OL Phase (Week 24 Onward)			Overall Exposed to MMB
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE Leading to Discontinuation of Study Drug	21 (32.8%)	22 (26.2%)	43 (29.1%)	61 (35.9%)
Number of Subjects with Treatment-Emergent AE Leading to Discontinuation of Study Drug, By System Organ Class, Preferred Term And Standard Toxicity Grade				
Blood and lymphatic system disorders (cont)				
Leukopenia	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Grade 1	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Neutropenia	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Grade 3	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	6 (9.4%)	3 (3.6%)	9 (6.1%)	11 (6.5%)
Grade 3	6 (9.4%)	3 (3.6%)	9 (6.1%)	10 (5.9%)
Grade 4	0	0	0	1 (0.6%)
Acute myeloid leukaemia	2 (3.1%)	1 (1.2%)	3 (2.0%)	3 (1.8%)
Grade 3	2 (3.1%)	1 (1.2%)	3 (2.0%)	3 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs and then PTs within an SOC were presented by descending order of the frequencies under the last column.
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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.1004: TEAE Leading to Premature Discontinuation of Study Drug (MMB) by SOC, PT, and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	OL Phase (Week 24 Onward)			Overall Exposed to MMB
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE Leading to Discontinuation of Study Drug	21 (32.8%)	22 (26.2%)	43 (29.1%)	61 (35.9%)
Number of Subjects with Treatment-Emergent AE Leading to Discontinuation of Study Drug, By System Organ Class, Preferred Term And Standard Toxicity Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Chronic myeloid leukaemia	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Grade 3	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Langerhans cell sarcoma	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Grade 3	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Leukoerythroblastosis	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Grade 3	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Ovarian clear cell carcinoma	0	0	0	1 (0.6%)
Grade 3	0	0	0	1 (0.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
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Source: t-ae-tox.sas V.03.05 Output file: t-teae-dc-drug-ol.pdf 29AUG2023: 9:44

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Number of Subjects with Treatment-Emergent AE Leading to Discontinuation of Study Drug, By System Organ Class, Preferred Term And Standard Toxicity Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Rectal cancer	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Grade 3	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Seminoma	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Grade 3	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Splenic marginal zone lymphoma	0	0	0	1 (0.6%)
Grade 4	0	0	0	1 (0.6%)
Transformation to acute myeloid leukaemia	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Grade 3	1 (1.6%)	0	1 (0.7%)	1 (0.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Number of Subjects with Treatment-Emergent AE Leading to Discontinuation of Study Drug, By System Organ Class, Preferred Term And Standard Toxicity Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Uterine cancer	0	0	0	1 (0.6%)
Grade 3	0	0	0	1 (0.6%)
Nervous system disorders	4 (6.3%)	3 (3.6%)	7 (4.7%)	9 (5.3%)
Grade 1	0	1 (1.2%)	1 (0.7%)	2 (1.2%)
Grade 2	1 (1.6%)	2 (2.4%)	3 (2.0%)	4 (2.4%)
Grade 3	2 (3.1%)	0	2 (1.4%)	2 (1.2%)
Grade 4	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Peripheral sensory neuropathy	2 (3.1%)	3 (3.6%)	5 (3.4%)	5 (2.9%)
Grade 1	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Grade 2	1 (1.6%)	2 (2.4%)	3 (2.0%)	3 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Number of Subjects with Treatment-Emergent AE Leading to Discontinuation of Study Drug, By System Organ Class, Preferred Term And Standard Toxicity Grade				
Nervous system disorders (cont)				
Peripheral sensory neuropathy (cont)				
Grade 3	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Dizziness	0	0	0	2 (1.2%)
Grade 1	0	0	0	1 (0.6%)
Grade 2	0	0	0	1 (0.6%)
Cerebrovascular accident	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Grade 4	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Paraesthesia	0	0	0	1 (0.6%)
Grade 1	0	0	0	1 (0.6%)
Peripheral sensorimotor neuropathy	1 (1.6%)	0	1 (0.7%)	1 (0.6%)

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Number of Subjects with Treatment-Emergent AE Leading to Discontinuation of Study Drug, By System Organ Class, Preferred Term And Standard Toxicity Grade				
Nervous system disorders (cont)				
Peripheral sensorimotor neuropathy (cont)				
Grade 3	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Infections and infestations	3 (4.7%)	2 (2.4%)	5 (3.4%)	7 (4.1%)
Grade 3	2 (3.1%)	1 (1.2%)	3 (2.0%)	4 (2.4%)
Grade 4	0	0	0	1 (0.6%)
Grade 5	1 (1.6%)	1 (1.2%)	2 (1.4%)	2 (1.2%)
Pneumonia	2 (3.1%)	1 (1.2%)	3 (2.0%)	3 (1.8%)
Grade 3	2 (3.1%)	1 (1.2%)	3 (2.0%)	3 (1.8%)
Escherichia sepsis	0	0	0	1 (0.6%)
Grade 4	0	0	0	1 (0.6%)

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Number of Subjects with Treatment-Emergent AE Leading to Discontinuation of Study Drug, By System Organ Class, Preferred Term And Standard Toxicity Grade				
Infections and infestations (cont)				
Pneumonia bacterial	0	0	0	1 (0.6%)
Grade 3	0	0	0	1 (0.6%)
Sepsis	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Grade 5	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Septic shock	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Grade 5	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Gastrointestinal disorders	1 (1.6%)	2 (2.4%)	3 (2.0%)	6 (3.5%)
Grade 1	1 (1.6%)	0	1 (0.7%)	3 (1.8%)
Grade 2	0	2 (2.4%)	2 (1.4%)	2 (1.2%)
Grade 3	0	0	0	1 (0.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
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Number of Subjects with Treatment-Emergent AE Leading to Discontinuation of Study Drug, By System Organ Class, Preferred Term And Standard Toxicity Grade				
Gastrointestinal disorders (cont)				
Diarrhoea	0	1 (1.2%)	1 (0.7%)	2 (1.2%)
Grade 2	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Grade 3	0	0	0	1 (0.6%)
Nausea	1 (1.6%)	0	1 (0.7%)	2 (1.2%)
Grade 1	1 (1.6%)	0	1 (0.7%)	2 (1.2%)
Abdominal pain	0	0	0	1 (0.6%)
Grade 1	0	0	0	1 (0.6%)
Anal incontinence	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Grade 2	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Dry mouth	0	1 (1.2%)	1 (0.7%)	1 (0.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
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Number of Subjects with Treatment-Emergent AE Leading to Discontinuation of Study Drug, By System Organ Class, Preferred Term And Standard Toxicity Grade				
Gastrointestinal disorders (cont)				
Dry mouth (cont)				
Grade 2	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Retching	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Grade 1	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Vomiting	0	0	0	1 (0.6%)
Grade 1	0	0	0	1 (0.6%)
General disorders and administration site conditions	0	2 (2.4%)	2 (1.4%)	6 (3.5%)
Grade 1	0	0	0	3 (1.8%)
Grade 2	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Grade 3	0	1 (1.2%)	1 (0.7%)	1 (0.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
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Number of Subjects with Treatment-Emergent AE Leading to Discontinuation of Study Drug, By System Organ Class, Preferred Term And Standard Toxicity Grade				
General disorders and administration site conditions (cont) (cont)				
Grade 5	0	0	0	1 (0.6%)
Malaise	0	1 (1.2%)	1 (0.7%)	3 (1.8%)
Grade 1	0	0	0	2 (1.2%)
Grade 3	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Fatigue	0	0	0	1 (0.6%)
Grade 1	0	0	0	1 (0.6%)
Impaired healing	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Grade 2	0	1 (1.2%)	1 (0.7%)	1 (0.6%)

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Number of Subjects with Treatment-Emergent AE Leading to Discontinuation of Study Drug, By System Organ Class, Preferred Term And Standard Toxicity Grade				
General disorders and administration site conditions (cont)				
Sudden death	0	0	0	1 (0.6%)
Grade 5	0	0	0	1 (0.6%)
Respiratory, thoracic and mediastinal disorders	2 (3.1%)	2 (2.4%)	4 (2.7%)	5 (2.9%)
Grade 2	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Grade 3	0	2 (2.4%)	2 (1.4%)	2 (1.2%)
Grade 4	1 (1.6%)	0	1 (0.7%)	2 (1.2%)
Dyspnoea	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Grade 3	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Epistaxis	1 (1.6%)	0	1 (0.7%)	1 (0.6%)

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Number of Subjects with Treatment-Emergent AE Leading to Discontinuation of Study Drug, By System Organ Class, Preferred Term And Standard Toxicity Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Epistaxis (cont)				
Grade 2	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Hypoxia	0	0	0	1 (0.6%)
Grade 4	0	0	0	1 (0.6%)
Pulmonary embolism	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Grade 3	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Respiratory failure	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Grade 4	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Cardiac disorders	1 (1.6%)	1 (1.2%)	2 (1.4%)	3 (1.8%)

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Number of Subjects with Treatment-Emergent AE Leading to Discontinuation of Study Drug, By System Organ Class, Preferred Term And Standard Toxicity Grade				
Cardiac disorders (cont) (cont)				
Grade 3	1 (1.6%)	1 (1.2%)	2 (1.4%)	3 (1.8%)
Atrial fibrillation	1 (1.6%)	1 (1.2%)	2 (1.4%)	2 (1.2%)
Grade 3	1 (1.6%)	1 (1.2%)	2 (1.4%)	2 (1.2%)
Cardiac failure	0	0	0	1 (0.6%)
Grade 3	0	0	0	1 (0.6%)
Cardiac failure congestive	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Grade 3	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Cardiomyopathy	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Grade 3	1 (1.6%)	0	1 (0.7%)	1 (0.6%)

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Number of Subjects with Treatment-Emergent AE Leading to Discontinuation of Study Drug, By System Organ Class, Preferred Term And Standard Toxicity Grade				
Cardiac disorders (cont)				
Tachycardia	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Grade 3	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Renal and urinary disorders	2 (3.1%)	1 (1.2%)	3 (2.0%)	3 (1.8%)
Grade 1	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Grade 3	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Grade 4	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Acute kidney injury	1 (1.6%)	1 (1.2%)	2 (1.4%)	2 (1.2%)
Grade 1	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Grade 3	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Nephropathy	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Grade 4	1 (1.6%)	0	1 (0.7%)	1 (0.6%)

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SAF-Anemic Analysis Set

	OL Phase (Week 24 Onward)			Overall Exposed to MMB
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE Leading to Discontinuation of Study Drug	21 (32.8%)	22 (26.2%)	43 (29.1%)	61 (35.9%)
Number of Subjects with Treatment-Emergent AE Leading to Discontinuation of Study Drug, By System Organ Class, Preferred Term And Standard Toxicity Grade				
Skin and subcutaneous tissue disorders	1 (1.6%)	2 (2.4%)	3 (2.0%)	3 (1.8%)
Grade 1	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Grade 3	1 (1.6%)	1 (1.2%)	2 (1.4%)	2 (1.2%)
Dermatitis allergic	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Grade 3	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Drug eruption	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Grade 3	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Hyperhidrosis	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Grade 1	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Toxic skin eruption	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Grade 3	1 (1.6%)	0	1 (0.7%)	1 (0.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs and then PTs within an SOC were presented by descending order of the frequencies under the last column.
The most severe AE within a PT was counted for each subject.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-tox.sas V.03.05 Output file: t-teae-dc-drug-ol.pdf 29AUG2023: 9:44

Table 3.1004: TEAE Leading to Premature Discontinuation of Study Drug (MMB) by SOC, PT, and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	OL Phase (Week 24 Onward)			Overall Exposed to MMB
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE Leading to Discontinuation of Study Drug	21 (32.8%)	22 (26.2%)	43 (29.1%)	61 (35.9%)
Number of Subjects with Treatment-Emergent AE Leading to Discontinuation of Study Drug, By System Organ Class, Preferred Term And Standard Toxicity Grade				
Vascular disorders	0	0	0	3 (1.8%)
Grade 1	0	0	0	2 (1.2%)
Grade 2	0	0	0	1 (0.6%)
Hypotension	0	0	0	2 (1.2%)
Grade 1	0	0	0	2 (1.2%)
Flushing	0	0	0	1 (0.6%)
Grade 2	0	0	0	1 (0.6%)
Investigations	1 (1.6%)	0	1 (0.7%)	2 (1.2%)
Grade 2	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Grade 4	0	0	0	1 (0.6%)
Blood creatinine increased	1 (1.6%)	0	1 (0.7%)	1 (0.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs and then PTs within an SOC were presented by descending order of the frequencies under the last column.
The most severe AE within a PT was counted for each subject.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.1004: TEAE Leading to Premature Discontinuation of Study Drug (MMB) by SOC, PT, and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	OL Phase (Week 24 Onward)			Overall Exposed to MMB
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE Leading to Discontinuation of Study Drug	21 (32.8%)	22 (26.2%)	43 (29.1%)	61 (35.9%)
Number of Subjects with Treatment-Emergent AE Leading to Discontinuation of Study Drug, By System Organ Class, Preferred Term And Standard Toxicity Grade				
Investigations (cont)				
Blood creatinine increased (cont)				
Grade 2	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Electrocardiogram QT prolonged	0	0	0	1 (0.6%)
Grade 4	0	0	0	1 (0.6%)
Endocrine disorders	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Grade 3	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Thyroiditis	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Grade 3	0	1 (1.2%)	1 (0.7%)	1 (0.6%)
Eye disorders	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Grade 4	1 (1.6%)	0	1 (0.7%)	1 (0.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs and then PTs within an SOC were presented by descending order of the frequencies under the last column.
The most severe AE within a PT was counted for each subject.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.1004: TEAE Leading to Premature Discontinuation of Study Drug (MMB) by SOC, PT, and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	OL Phase (Week 24 Onward)			Overall Exposed to MMB
	Continuing (MMB->MMB) (N=64)	Switch (RUX->MMB) (N=84)	Total (N=148)	Total (N=170)
Number of Subjects with Any Treatment-Emergent AE Leading to Discontinuation of Study Drug	21 (32.8%)	22 (26.2%)	43 (29.1%)	61 (35.9%)
Number of Subjects with Treatment-Emergent AE Leading to Discontinuation of Study Drug, By System Organ Class, Preferred Term And Standard Toxicity Grade				
Eye disorders (cont)				
Eye haemorrhage	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Grade 4	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Eye pain	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Grade 3	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Vision blurred	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Grade 3	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Hepatobiliary disorders	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Grade 3	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Liver disorder	1 (1.6%)	0	1 (0.7%)	1 (0.6%)
Grade 3	1 (1.6%)	0	1 (0.7%)	1 (0.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs and then PTs within an SOC were presented by descending order of the frequencies under the last column.
The most severe AE within a PT was counted for each subject.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

1.10.6 UESI

GSK Oncology
Study GS-US-352-0101

Table 3.2501: Any TE AESI
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)			
				Continuing	Switch		
	MMB (N=86)	RUX (N=94)	Total (N=180)	(MMB->MMB) (N=64)	(RUX->MMB) (N=84)	Total (N=148)	
Number of subjects, n(%)	79 (91.9%)	88 (93.6%)	167 (92.8%)	58 (90.6%)	81 (96.4%)	139 (93.9%)	
Unadjusted Relative Risk (95% CI)	0.98 (0.90, 1.07)						
p-value [1]	0.65						
Unadjusted Odds Ratio (95% CI)	0.77 (0.25, 2.39)						
p-value [1]	0.65						
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.09, 0.06)						

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-gba.sas V.03.05 Output file: t-aesum-aesi-gba.pdf 29AUG2023: 8:53

GSK Oncology
Study GS-US-352-0101

Table 3.2701: Any TE AESI of Grade 3 or more
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=86)	RUX (N=94)	Total (N=180)	(MMB->MMB) (N=64)	(RUX->MMB) (N=84)	Total (N=148)
Number of subjects, n(%)	33 (38.4%)	26 (27.7%)	59 (32.8%)	40 (62.5%)	46 (54.8%)	86 (58.1%)
Unadjusted Relative Risk (95% CI)	1.39 (0.91, 2.12)					
p-value [1]	0.13					
Unadjusted Odds Ratio (95% CI)	1.63 (0.87, 3.05)					
p-value [1]	0.13					
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.03, 0.24)					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-gba.sas V.03.05 Output file: t-aesum-aesi-gge3-gba.pdf 29AUG2023: 8:53

Table 3.2601: Any TE AESI of Grade 2 or less
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=86)	RUX (N=94)	Total (N=180)	(MMB->MMB) (N=64)	(RUX->MMB) (N=84)	Total (N=148)
Number of subjects, n(%)	76 (88.4%)	87 (92.6%)	163 (90.6%)	57 (89.1%)	80 (95.2%)	137 (92.6%)
Unadjusted Relative Risk (95% CI)	0.95 (0.87, 1.05)					
p-value [1]	0.34					
Unadjusted Odds Ratio (95% CI)	0.61 (0.22, 1.69)					
p-value [1]	0.34					
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.13, 0.04)					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-gba.sas V.03.05 Output file: t-aesum-aesi-gle2-gba.pdf 29AUG2023: 8:53

GSK Oncology
Study GS-US-352-0101

Table 3.2801: Any Serious TE AESI
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)			
				Continuing	Switch		
	MMB (N=86)	RUX (N=94)	Total (N=180)	(MMB->MMB) (N=64)	(RUX->MMB) (N=84)	Total (N=148)	
Number of subjects, n(%)	24 (27.9%)	19 (20.2%)	43 (23.9%)	34 (53.1%)	37 (44.0%)	71 (48.0%)	
Unadjusted Relative Risk (95% CI)	1.38 (0.82, 2.34)						
p-value [1]	0.23						
Unadjusted Odds Ratio (95% CI)	1.53 (0.77, 3.04)						
p-value [1]	0.23						
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.05, 0.20)						

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-gba.sas V.03.05 Output file: t-aesum-aesi-ser-gba.pdf 29AUG2023: 8:53

Table 3.3901: TEAEs of Cataract MST
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=86)	RUX (N=94)	Total (N=180)	(MMB->MMB) (N=64)	(RUX->MMB) (N=84)	Total (N=148)
Number of subjects, n(%)	3 (3.5%)	1 (1.1%)	4 (2.2%)	6 (9.4%)	3 (3.6%)	9 (6.1%)
Unadjusted Relative Risk (95% CI)	3.28 (0.35, 30.93)					
p-value [1]	0.30					
Unadjusted Odds Ratio (95% CI)	3.36 (0.34, 32.95)					
p-value [1]	0.30					
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.02, 0.07)					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-cat-gba.sas V.03.05 Output file: t-aesum-cat-gba.pdf 29AUG2023: 9:41

Table 3.4101: TEAEs of Cataract MST of Grade 3 or more
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=86)	RUX (N=94)	Total (N=180)	(MMB->MMB) (N=64)	(RUX->MMB) (N=84)	Total (N=148)
Number of subjects, n(%)	0	0	0	2 (3.1%)	1 (1.2%)	3 (2.0%)
Unadjusted Relative Risk (95% CI)	NE					
p-value [1]	NE					
Unadjusted Odds Ratio (95% CI)	NE					
p-value [1]	NE					
Unadjusted Absolute Risk Difference (95% CI)	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-cat-gba.sas V.03.05 Output file: t-aesum-cat-gge3-gba.pdf 29AUG2023: 9:41

Table 3.4001: TEAEs of Cataract MST of Grade 2 or less
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)			
				Continuing	Switch		
	MMB (N=86)	RUX (N=94)	Total (N=180)	(MMB->MMB) (N=64)	(RUX->MMB) (N=84)	Total (N=148)	
Number of subjects, n(%)	3 (3.5%)	1 (1.1%)	4 (2.2%)	5 (7.8%)	2 (2.4%)	7 (4.7%)	
Unadjusted Relative Risk (95% CI)	3.28 (0.35, 30.93)						
p-value [1]	0.30						
Unadjusted Odds Ratio (95% CI)	3.36 (0.34, 32.95)						
p-value [1]	0.30						
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.02, 0.07)						

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-cat-gba.sas V.03.05 Output file: t-aesum-cat-gle2-gba.pdf 29AUG2023: 9:41

Table 3.4201: Serious TEAEs of Cataract MST
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=86)	RUX (N=94)	Total (N=180)	(MMB->MMB) (N=64)	(RUX->MMB) (N=84)	Total (N=148)
Number of subjects, n(%)	0	0	0	1 (1.6%)	1 (1.2%)	2 (1.4%)
Unadjusted Relative Risk (95% CI)	NE					
p-value [1]	NE					
Unadjusted Odds Ratio (95% CI)	NE					
p-value [1]	NE					
Unadjusted Absolute Risk Difference (95% CI)	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-cat-gba.sas V.03.05 Output file: t-aesum-cat-ser-gba.pdf 29AUG2023: 9:41

Table 3.4301: TEAEs of First Dose Effect
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=86)	RUX (N=94)	Total (N=180)	(MMB->MMB) (N=64)	(RUX->MMB) (N=84)	Total (N=148)
Number of subjects, n(%)	5 (5.8%)	1 (1.1%)	6 (3.3%)	-	1 (1.2%)	-
Unadjusted Relative Risk (95% CI)	5.47 (0.65, 45.85)					
p-value [1]	0.12					
Unadjusted Odds Ratio (95% CI)	5.74 (0.66, 50.16)					
p-value [1]	0.11					
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.01, 0.10)					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-fds-gba.sas V.03.05 Output file: t-aesum-fds-gba.pdf 29AUG2023: 8:54

Table 3.4501: TEAEs of First Dose Effect of Grade 3 or more
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=86)	RUX (N=94)	Total (N=180)	(MMB->MMB) (N=64)	(RUX->MMB) (N=84)	Total (N=148)
Number of subjects, n(%)	1 (1.2%)	0	1 (0.6%)	-	0	-
Unadjusted Relative Risk (95% CI)	3.28 (0.14, 79.36)					
p-value [1]	0.47					
Unadjusted Odds Ratio (95% CI)	3.32 (0.13, 82.49)					
p-value [1]	0.46					
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.02, 0.04)					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-fds-gba.sas V.03.05 Output file: t-aesum-fds-gge3-gba.pdf 29AUG2023: 8:54

Table 3.4401: TEAEs of First Dose Effect of Grade 2 or less
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=86)	RUX (N=94)	Total (N=180)	(MMB->MMB) (N=64)	(RUX->MMB) (N=84)	Total (N=148)
Number of subjects, n(%)	4 (4.7%)	1 (1.1%)	5 (2.8%)	-	1 (1.2%)	-
Unadjusted Relative Risk (95% CI)	4.37 (0.50, 38.36)					
p-value [1]	0.18					
Unadjusted Odds Ratio (95% CI)	4.54 (0.50, 41.41)					
p-value [1]	0.18					
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.01, 0.08)					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-fds-gba.sas V.03.05 Output file: t-aesum-fds-gle2-gba.pdf 29AUG2023: 8:54

Table 3.4601: Serious TEAEs of First Dose Effect
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=86)	RUX (N=94)	Total (N=180)	(MMB->MMB) (N=64)	(RUX->MMB) (N=84)	Total (N=148)
Number of subjects, n(%)	1 (1.2%)	0	1 (0.6%)	-	0	-
Unadjusted Relative Risk (95% CI)	3.28 (0.14, 79.36)					
p-value [1]	0.47					
Unadjusted Odds Ratio (95% CI)	3.32 (0.13, 82.49)					
p-value [1]	0.46					
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.02, 0.04)					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-fds-gba.sas V.03.05 Output file: t-aesum-fds-ser-gba.pdf 29AUG2023: 8:54

Table 3.3501: TEAEs of Non-Hematological MST
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=86)	RUX (N=94)	Total (N=180)	(MMB->MMB) (N=64)	(RUX->MMB) (N=84)	Total (N=148)
Number of subjects, n(%)	79 (91.9%)	88 (93.6%)	167 (92.8%)	58 (90.6%)	81 (96.4%)	139 (93.9%)
Unadjusted Relative Risk (95% CI)	0.98 (0.90, 1.07)					
p-value [1]	0.65					
Unadjusted Odds Ratio (95% CI)	0.77 (0.25, 2.39)					
p-value [1]	0.65					
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.09, 0.06)					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-gba.sas V.03.05 Output file: t-aesum-nh-gba.pdf 29AUG2023: 8:54

Table 3.3701: TEAEs of Non-Hematological MST of Grade 3 or more
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=86)	RUX (N=94)	Total (N=180)	(MMB->MMB) (N=64)	(RUX->MMB) (N=84)	Total (N=148)
Number of subjects, n(%)	33 (38.4%)	26 (27.7%)	59 (32.8%)	40 (62.5%)	46 (54.8%)	86 (58.1%)
Unadjusted Relative Risk (95% CI)	1.39 (0.91, 2.12)					
p-value [1]	0.13					
Unadjusted Odds Ratio (95% CI)	1.63 (0.87, 3.05)					
p-value [1]	0.13					
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.03, 0.24)					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-gba.sas V.03.05 Output file: t-aesum-nh-gge3-gba.pdf 29AUG2023: 8:54

Table 3.3601: TEAEs of Non-Hematological MST of Grade 2 or less
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=86)	RUX (N=94)	Total (N=180)	(MMB->MMB) (N=64)	(RUX->MMB) (N=148)	Total
Number of subjects, n(%)	76 (88.4%)	87 (92.6%)	163 (90.6%)	57 (89.1%)	80 (95.2%)	137 (92.6%)
Unadjusted Relative Risk (95% CI)	0.95 (0.87, 1.05)					
p-value [1]	0.34					
Unadjusted Odds Ratio (95% CI)	0.61 (0.22, 1.69)					
p-value [1]	0.34					
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.13, 0.04)					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-gba.sas V.03.05 Output file: t-aesum-nh-gle2-gba.pdf 29AUG2023: 8:54

Table 3.3801: Serious TEAEs of Non-Hematological MST
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=86)	RUX (N=94)	Total (N=180)	(MMB->MMB) (N=64)	(RUX->MMB) (N=84)	Total (N=148)
Number of subjects, n(%)	24 (27.9%)	19 (20.2%)	43 (23.9%)	34 (53.1%)	37 (44.0%)	71 (48.0%)
Unadjusted Relative Risk (95% CI)	1.38 (0.82, 2.34)					
p-value [1]	0.23					
Unadjusted Odds Ratio (95% CI)	1.53 (0.77, 3.04)					
p-value [1]	0.23					
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.05, 0.20)					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-gba.sas V.03.05 Output file: t-aesum-nh-ser-gba.pdf 29AUG2023: 8:54

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Table 3.3401: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) leading to discontinuation of MMB\MMB Matched Placebo Double-Blind Phase, and Open-Label Phase (Week 24 Onward)

SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=86)	RUX (N=94)	Total (N=180)	(MMB->MMB) (N=64)	(RUX->MMB) (N=84)	Total (N=148)
Number of subjects, n(%)	0	0	0	3 (4.7%)	3 (3.6%)	6 (4.1%)
Unadjusted Relative Risk (95% CI)	NE					
p-value [1]	NE					
Unadjusted Odds Ratio (95% CI)	NE					
p-value [1]	NE					
Unadjusted Absolute Risk Difference (95% CI)	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.

TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019

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Study GS-US-352-0101

Table 3.4701: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) leading to discontinuation of RUX\RUX Matched Placebo Double-Blind Phase, and Open-Label Phase (Week 24 Onward)

SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.

TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019

Table 3.3001: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only)
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=86)	RUX (N=94)	Total (N=180)	(MMB->MMB) (N=64)	(RUX->MMB) (N=84)	Total (N=148)
Number of subjects, n(%)	10 (11.6%)	5 (5.3%)	15 (8.3%)	10 (15.6%)	14 (16.7%)	24 (16.2%)
Unadjusted Relative Risk (95% CI)	2.19 (0.78, 6.14)					
p-value [1]	0.14					
Unadjusted Odds Ratio (95% CI)	2.34 (0.77, 7.15)					
p-value [1]	0.14					
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.02, 0.14)					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-pn-gba.sas V.03.05 Output file: t-aesum-pn-gba.pdf 29AUG2023: 8:56

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Study GS-US-352-0101

Table 3.3201: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 3 or more
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=86)	RUX (N=94)	Total (N=180)	(MMB->MMB) (N=64)	(RUX->MMB) (N=84)	Total (N=148)
Number of subjects, n(%)	0	0	0	2 (3.1%)	2 (2.4%)	4 (2.7%)
Unadjusted Relative Risk (95% CI)	NE					
p-value [1]	NE					
Unadjusted Odds Ratio (95% CI)	NE					
p-value [1]	NE					
Unadjusted Absolute Risk Difference (95% CI)	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-pn-gba.sas V.03.05 Output file: t-aesum-pn-gge3-gba.pdf 29AUG2023: 8:56

Table 3.3101: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 2 or less
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=86)	RUX (N=94)	Total (N=180)	(MMB->MMB) (N=64)	(RUX->MMB) (N=84)	Total (N=148)
Number of subjects, n(%)	10 (11.6%)	5 (5.3%)	15 (8.3%)	8 (12.5%)	14 (16.7%)	22 (14.9%)
Unadjusted Relative Risk (95% CI)	2.19 (0.78, 6.14)					
p-value [1]	0.14					
Unadjusted Odds Ratio (95% CI)	2.34 (0.77, 7.15)					
p-value [1]	0.14					
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.02, 0.14)					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-pn-gba.sas V.03.05 Output file: t-aesum-pn-gle2-gba.pdf 29AUG2023: 8:56

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Study GS-US-352-0101

Table 3.3301: Serious TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only)
Double-Blind Phase, and Open-Label Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	DB Phase			OL Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=86)	RUX (N=94)	Total (N=180)	(MMB->MMB) (N=64)	(RUX->MMB) (N=84)	Total (N=148)
Number of subjects, n(%)	0	0	0	1 (1.6%)	0	1 (0.7%)
Unadjusted Relative Risk (95% CI)	NE					
p-value [1]	NE					
Unadjusted Odds Ratio (95% CI)	NE					
p-value [1]	NE					
Unadjusted Absolute Risk Difference (95% CI)	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.

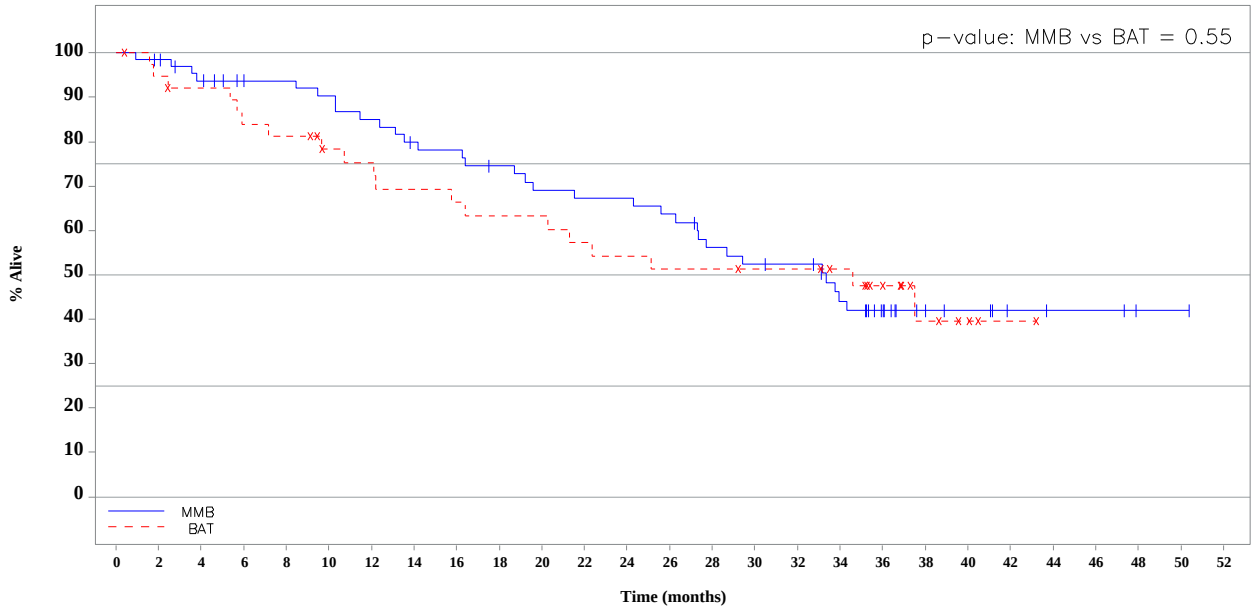
Data Extracted: CRF data: 01JUL2019

2 SIMPLIFY-2

2.1 Gesamtüberleben

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Study GS-US-352-1214

Figure 2.2902: Kaplan-Meier Plot of Overall Survival
Overall (Randomized + Extended) Treatment Phase
ITT-Anemic Analysis Set



N at Risk (Events)

MMB	66 (0)	64 (1)	59 (4)	55 (4)	54 (4)	52 (6)	49 (9)	45 (12)	44 (13)	41 (15)	38 (18)	37 (19)	37 (19)	35 (21)	30 (25)	28 (27)	27 (27)	21 (31)	15 (32)	9 (32)	7 (32)	4 (32)	3 (32)	3 (32)	1 (32)	1 (32)	0 (32)
BAT	39 (0)	36 (2)	34 (3)	31 (6)	30 (7)	26 (8)	25 (9)	23 (11)	22 (12)	21 (13)	21 (13)	19 (15)	18 (16)	17 (17)	17 (17)	16 (17)	16 (17)	14 (17)	10 (18)	5 (19)	3 (19)	1 (19)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-os-comb.sas V.03.05 Output file: g-os-comb.pdf 25AUG2023:12:38

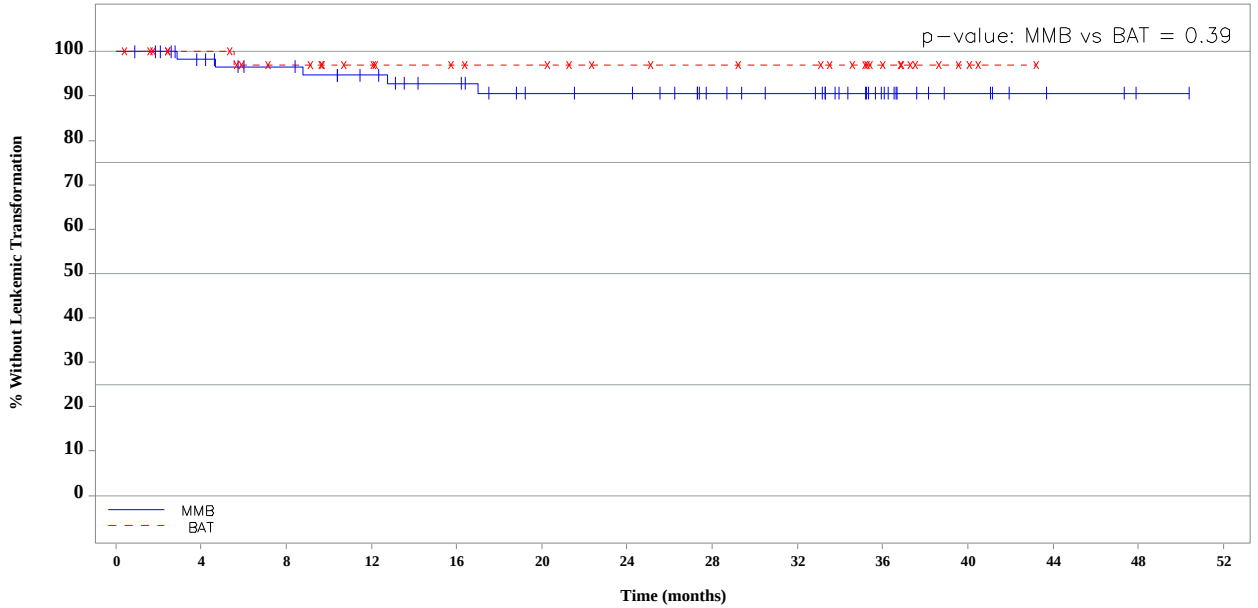
Table 2.5901: Overall Survival Analysis
Randomized Treatment Phase and the Overall (Randomized + Extended) Treatment Phase
ITT-Anemic Analysis Set

	Overall Treatment Phase		Randomized Treatment Phase	
	MMB (N=66)	BAT (N=39)	MMB (N=66)	BAT (N=39)
Subjects with Event				
Death, n(%)	32 (48.5%)	19 (48.7%)	4 (6.1%)	5 (12.8%)
Subjects Died in RT Phase	4 (12.5%)	5 (26.3%)	4 (100.0%)	5 (100.0%)
Subjects Died in ET Phase	11 (34.4%)	3 (15.8%)	0	0
Subjects Died in follow up	17 (53.1%)	11 (57.9%)	0	0
Censor				
Subjects Censored, n(%)	34 (51.5%)	20 (51.3%)	62 (93.9%)	34 (87.2%)
Kaplan-Meier Estimate of Overall Survival (Months)				
25-percentile (95% CI)	16.43 (11.47, 25.59)	12.12 (5.36, 20.27)	NE (NE, NE)	NE (5.36, NE)
Median (95% CI)	33.35 (25.59, NE)	34.60 (15.77, NE)	NE (NE, NE)	NE (NE, NE)
75-percentile (95% CI)	NE (NE, NE)	NE (37.52, NE)	NE (NE, NE)	NE (NE, NE)
Min, Max	0.92, 50.40	0.43, 43.20	0.92, 6.80	0.43, 6.54
Stratified Log-Rank Test p-value	0.55		0.29	
Adjusted Hazard Ratio (95% CI)	0.88 (0.49, 1.57)		0.46 (0.12, 1.74)	
Unstratified Log-Rank Test p-value	0.75		0.28	
Unadjusted Hazard Ratio (95% CI)	0.91 (0.52, 1.61)		0.49 (0.13, 1.85)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Death in the RT phase is death occurring on or after the 1st RT dose up to the earliest of the last RT dose + 30 days, or the 1st ET dose -1 day.
Death in the ET phase is death occurring on or after 1st ET dose up to the last ET MMB dose + 30 days.
Death in the follow-up phase is death occurring after 30 days of the last dose in RT or ET phase, whichever the latest.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-os-comb.sas V.03.05 Output file: t-os-comb.pdf 24AUG2023:16:45

2.2 Leukämische Transformation

Figure 2.3201: Kaplan-Meier Plot of Time to Leukemic Transformation
Overall (Randomized + Extended) Treatment Phase
ITT-Anemic Analysis Set



N at Risk (Events)

MMB	66 (0)	59 (1)	54 (2)	49 (3)	44 (4)	38 (5)	37 (5)	30 (5)	27 (5)	15 (5)	7 (5)	3 (5)	1 (5)	0 (5)
BAT	39 (0)	34 (0)	29 (1)	25 (1)	22 (1)	21 (1)	18 (1)	17 (1)	16 (1)	10 (1)	3 (1)	0 (1)	0 (1)	0 (1)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-tte-It-comb.sas V.03.05 Output file: g-tte-It-comb.pdf 25AUG2023:12:38

Table 2.6101: Analysis of Time to Leukemic Transformation
Randomized Treatment Phase and the Overall (Randomized + Extended) Treatment Phase
ITT-Anemic Analysis Set

	Overall Treatment Phase		Randomized Treatment Phase	
	MMB (N=66)	BAT (N=39)	MMB (N=66)	BAT (N=39)
Subjects with Event				
Leukemic Transformation, n(%)	5 (7.6%)	1 (2.6%)	2 (3.0%)	1 (2.6%)
Censor				
Subjects Censored, n(%)	61 (92.4%)	38 (97.4%)	64 (97.0%)	38 (97.4%)
Kaplan-Meier Estimate of Time to Leukemic Transformation (Months)				
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (5.55, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Min, Max	0.92, 50.40	0.43, 43.20	0.92, 7.00	0.43, 6.14
Stratified Log-Rank Test p-value	0.39		0.67	
Adjusted Hazard Ratio (95% CI)	2.67 (0.30, 23.43)		1.51 (0.13, 17.97)	
Unstratified Log-Rank Test p-value	0.34		0.84	
Unadjusted Hazard Ratio (95% CI)	2.72 (0.32, 23.32)		1.28 (0.12, 14.14)	

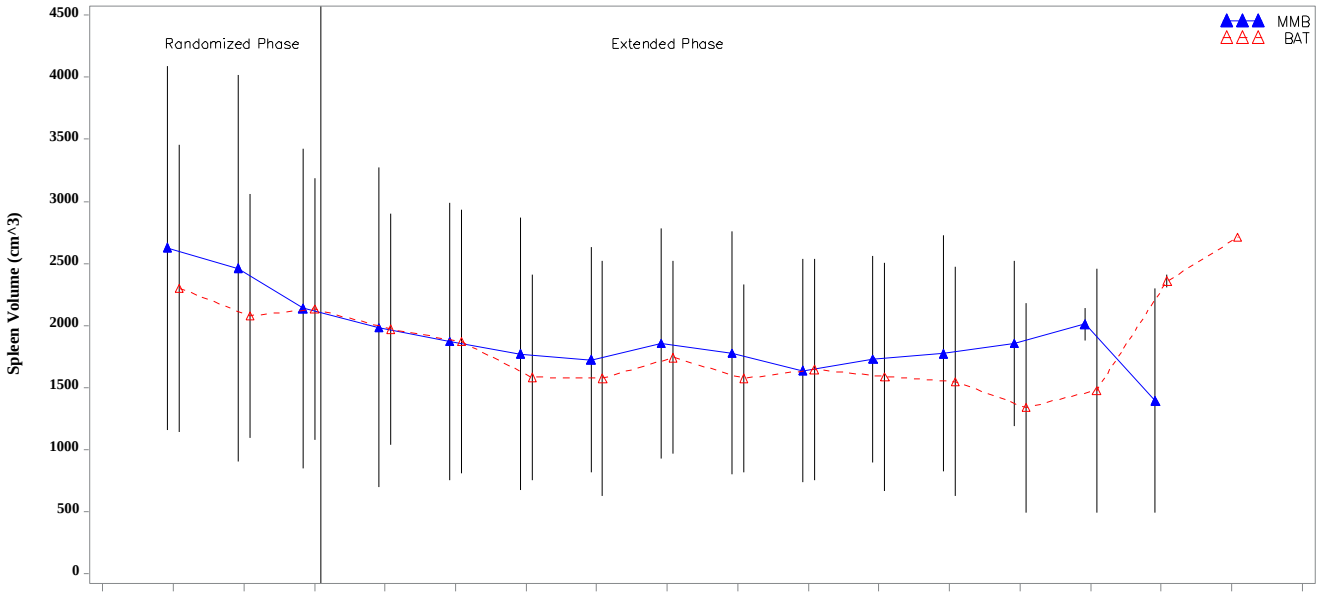
ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-lt.sas V.03.05 Output file: t-tte-lt.pdf 24AUG2023:16:46

2.3 Milzansprechen

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Figure 2.0503: Mean (+/- StD) Plots of Spleen Volume by MRI or CT, Change and % Change from Baseline (including Baseline)
Combination of Randomized Treatment Phase and Extended Treatment Phase
ITT-Anemic Analysis Set

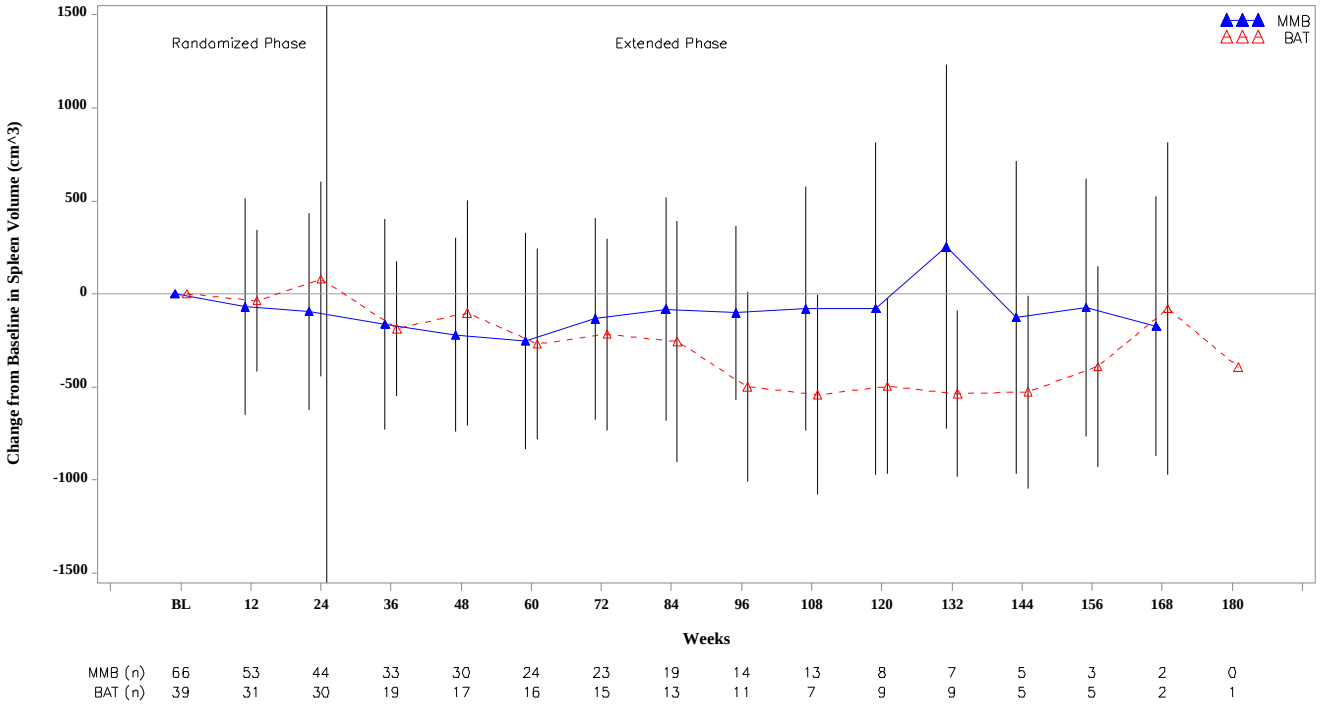


	BL	12	24	36	48	60	72	84	96	108	120	132	144	156	168	180
MMB (n)	66	53	44	33	30	24	23	19	14	13	8	7	5	3	2	0
BAT (n)	39	31	30	19	17	16	15	13	11	7	9	9	5	5	2	1

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is the last assessment prior to or on the date of randomization.
MRI = Magnetic Resonance Imaging.
CT = Computerized Tomography.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-adhoc-line-comb.sas V.03.05 Output file: adhoc-g-spv-line-pchg-rt-et.pdf 24AUG2023:15:32

Figure 2.0503: Mean (+/- StD) Plots of Spleen Volume by MRI or CT, Change and % Change from Baseline (including Baseline)
Combination of Randomized Treatment Phase and Extended Treatment Phase
ITT-Anemic Analysis Set

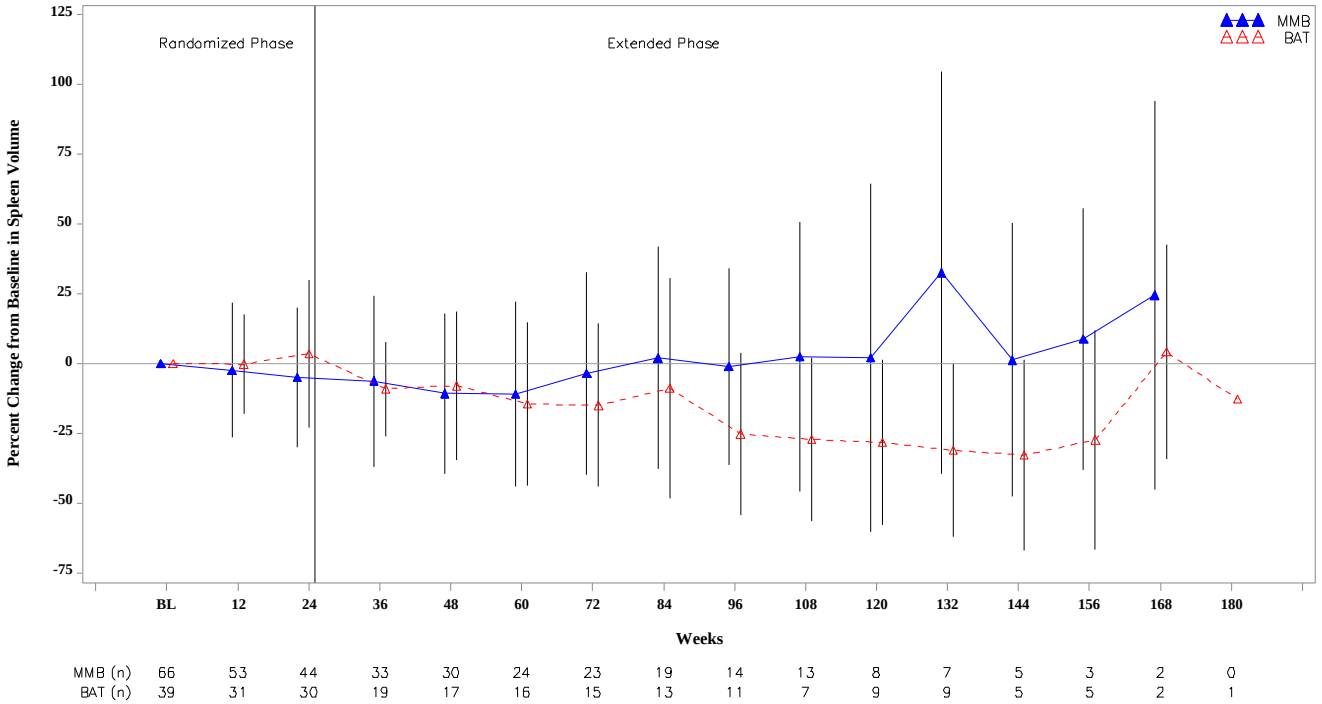


	BL	12	24	36	48	60	72	84	96	108	120	132	144	156	168	180
MMB (n)	66	53	44	33	30	24	23	19	14	13	8	7	5	3	2	0
BAT (n)	39	31	30	19	17	16	15	13	11	7	9	9	5	5	2	1

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is the last assessment prior to or on the date of randomization.
MRI = Magnetic Resonance Imaging.
CT = Computerized Tomography.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-adhoc-line-comb.sas V.03.05 Output file: adhoc-g-spv-line-pchg-rt-et.pdf 24AUG2023:15:32

Figure 2.0503: Mean (+/- StD) Plots of Spleen Volume by MRI or CT, Change and % Change from Baseline (including Baseline)
Combination of Randomized Treatment Phase and Extended Treatment Phase
ITT-Anemic Analysis Set

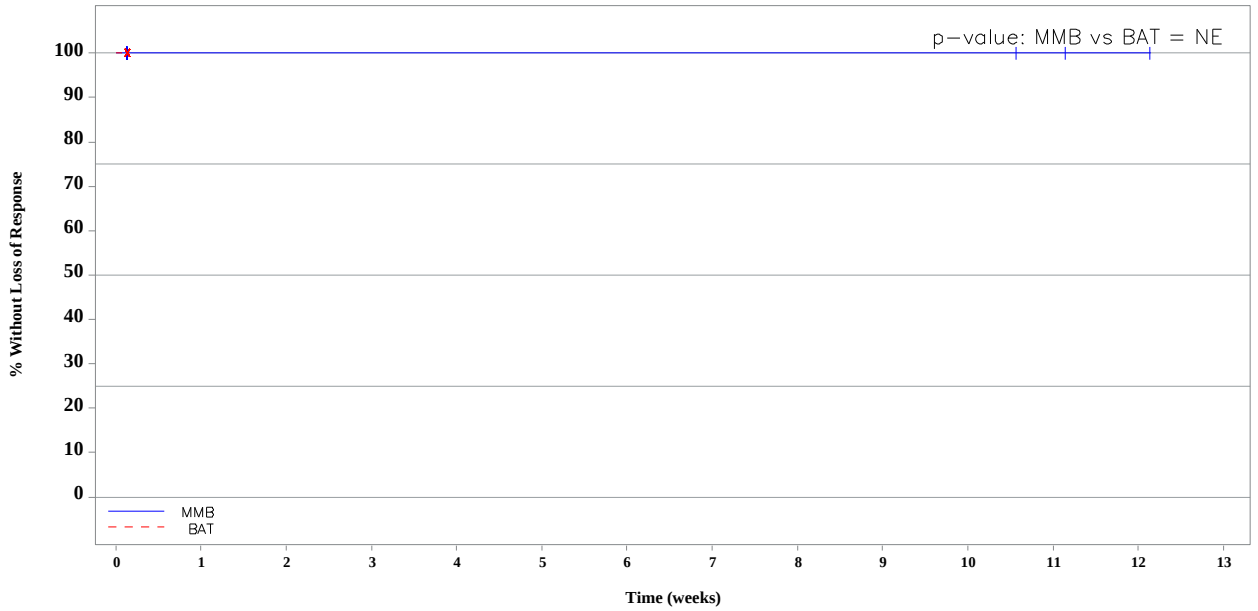


	BL	12	24	36	48	60	72	84	96	108	120	132	144	156	168	180
MMB (n)	66	53	44	33	30	24	23	19	14	13	8	7	5	3	2	0
BAT (n)	39	31	30	19	17	16	15	13	11	7	9	9	5	5	2	1

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is the last assessment prior to or on the date of randomization.
MRI = Magnetic Resonance Imaging.
CT = Computerized Tomography.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-adhoc-line-comb.sas V.03.05 Output file: adhoc-g-spv-line-pchg-rt-et.pdf 24AUG2023:15:33

Figure 2.0301: Kaplan-Meier Plot of Duration of MRI/CT Splenic Response
Randomized Treatment Phase
ITT-Anemic Analysis Set



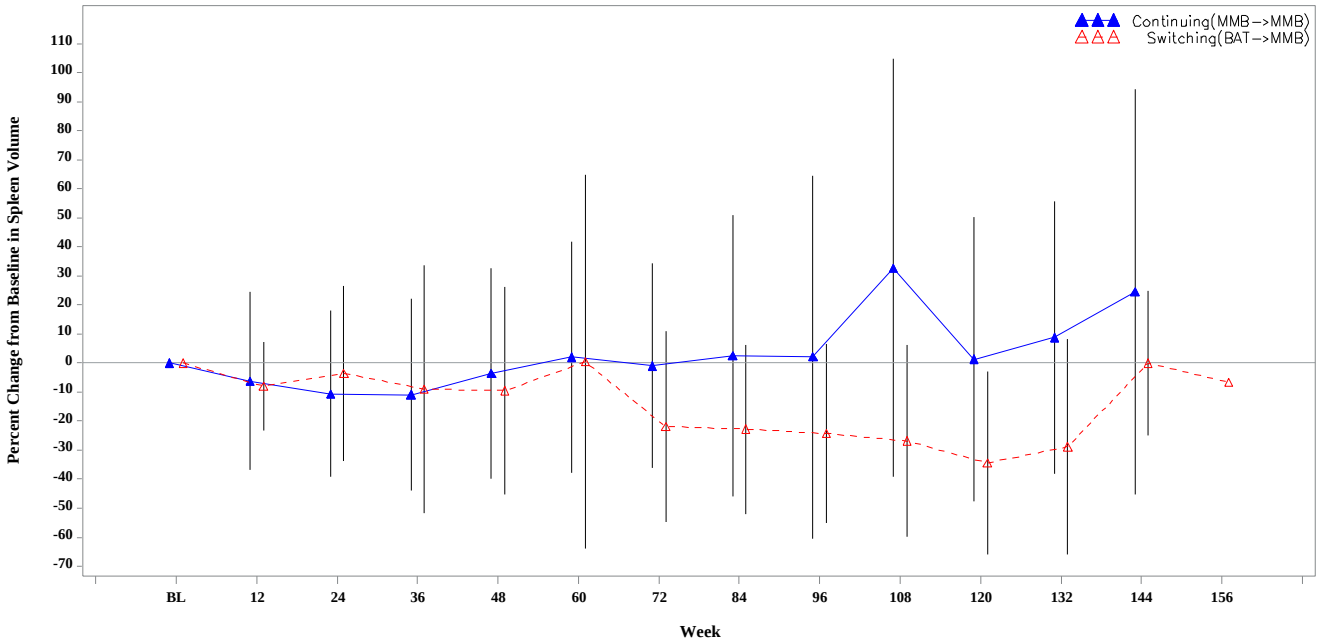
N at Risk (Events)

MMB	66 (0)	3 (0)	3 (0)	3 (0)	3 (0)	3 (0)	3 (0)	3 (0)	3 (0)	3 (0)	3 (0)	2 (0)	1 (0)	0 (0)
BAT	39 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL. NE = Not estimable.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-dur-sr-rt_Sep2023.sas V.03.05 Output file: g-dur-sr-rt.pdf 13OCT2023:13:56

Figure 2.0502: Mean (+/- StD) Plots of % Change from Baseline (including Baseline) for Spleen Volume by MRI or CT
Extended Treatment Phase (Week 24 Onward)
ITT-Anemic Analysis Set

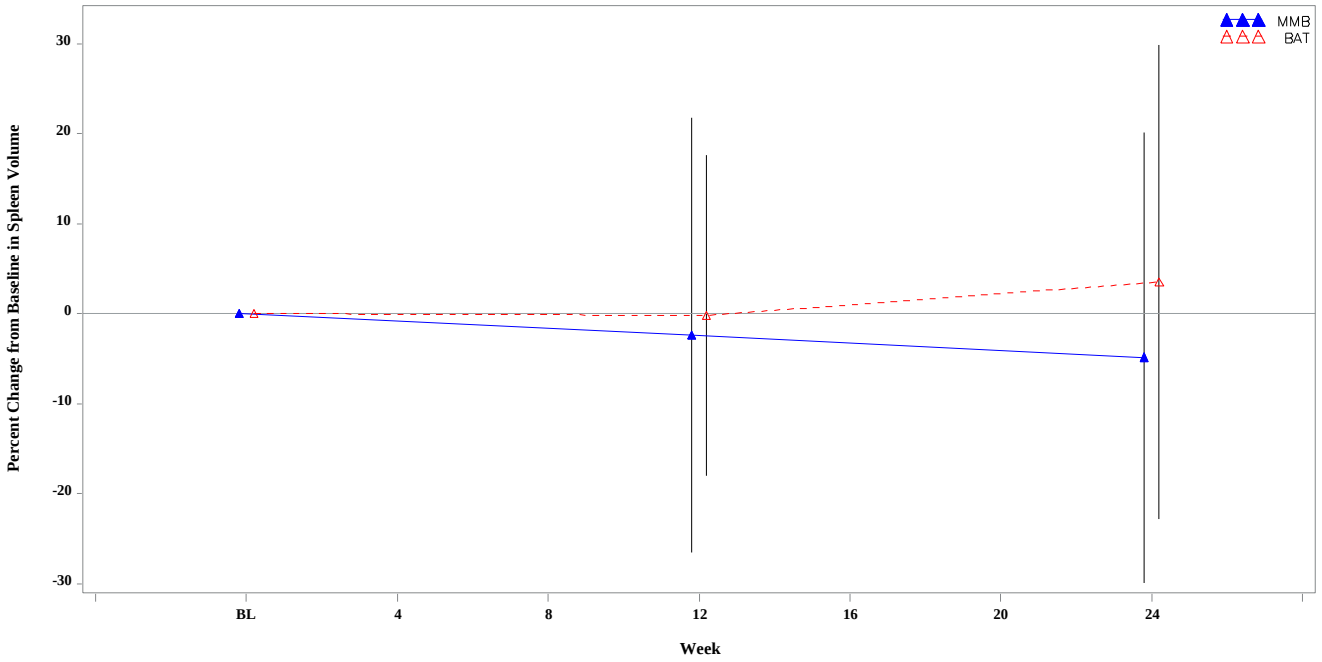


Continuing(MMB->MMB) 43	33	30	24	23	19	14	13	8	7	5	3	2	0
Switching(BAT->MMB) 30	19	17	16	15	13	11	7	9	9	5	5	2	1

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MRI = Magnetic Resonance Imaging
CT = Computerized Tomography
Switching group switches from BAT to MMB at Week 24

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-spv-line-pchg-et.pdf 24AUG2023:16:50

Figure 2.0501: Mean (+/- StD) Plots of % Change from Baseline (including Baseline) for Spleen Volume by MRI or CT
Randomized Treatment Phase
ITT-Anemic Analysis Set



MMB (n)	66	53	44
BAT (n)	39	31	30

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MRI = Magnetic Resonance Imaging
CT = Computerized Tomography

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-spv-line-pchg-rt.pdf 24AUG2023:16:50

Table 2.1201: Analysis of Spleen Volume and % Change from Baseline
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=43)	Switch (BAT -> MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Spleen Volume at Baseline(cm^3)					
N	43	30	73	66	96
Mean (SD)	2333.5 (1300.53)	2199.7 (1056.22)	2278.5 (1200.15)	2625.5 (1467.27)	2492.4 (1361.23)
Median	2357.6	2101.8	2173.3	2576.8	2425.6
Q1, Q3	1329.8, 3073.5	1237.6, 2904.8	1329.8, 3064.2	1340.9, 3541.6	1335.3, 3202.5
Min, Max	392.4, 6740.4	429.6, 4999.9	392.4, 6740.4	392.4, 6740.4	392.4, 6740.4
Minimum SPV in the Postbaseline Treatment Period					
N	38	25	63	56	81
Mean (SD)	1949.4 (1134.38)	1690.3 (1025.03)	1846.6 (1091.33)	2280.0 (1515.09)	2098.0 (1403.03)
Median	1909.9	1743.1	1852.8	1896.6	1847.3
Q1, Q3	929.8, 2516.7	721.0, 2417.9	909.1, 2458.0	968.9, 3227.7	947.7, 2826.4
Min, Max	168.5, 4677.4	275.6, 4287.7	168.5, 4677.4	168.5, 6072.8	168.5, 6072.8
Percent of Minimum SPV Change from Baseline in the Postbaseline Treatment Period					
N	38	25	63	56	81
Mean (SD)	-9.4 (32.26)	-18.3 (24.92)	-12.9 (29.68)	-10.1 (26.39)	-12.6 (26.07)
Median	-14.4	-14.2	-14.2	-10.6	-11.3
Q1, Q3	-28.1, 11.9	-36.4, 0.8	-30.9, 7.6	-28.3, 6.5	-28.4, 4.4
Min, Max	-63.9, 74.4	-75.5, 21.2	-75.5, 74.4	-63.9, 47.4	-75.5, 47.4

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (BAT->MMB) group, the baseline is the last assessment prior to or on the date of the 1st dose of MMB in the ET phase.
For Continuing (MMB->MMB) group, the baseline is the last assessment prior to or on the date of randomization.

**Table 2.1201: Analysis of Spleen Volume and % Change from Baseline
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set**

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=43)	Switch (BAT -> MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Maximum SPV in the Postbaseline Treatment Period					
N	38	25	63	56	81
Mean (SD)	2344.3 (1233.69)	2132.5 (1089.10)	2260.2 (1174.03)	2706.5 (1509.95)	2529.3 (1412.26)
Median	2403.6	2127.8	2321.6	2581.6	2362.7
Q1, Q3	1313.6, 3031.0	1087.8, 2711.9	1224.3, 3001.7	1466.4, 3565.7	1395.6, 3247.2
Min, Max	198.1, 6122.2	448.6, 4329.9	198.1, 6122.2	268.2, 6122.2	268.2, 6122.2
Percent of Maximum SPV Change from Baseline in the Postbaseline Treatment Period					
N	38	25	63	56	81
Mean (SD)	12.4 (41.98)	9.5 (44.73)	11.2 (42.76)	12.8 (35.74)	11.8 (38.48)
Median	2.0	1.8	1.8	3.6	2.8
Q1, Q3	-14.6, 32.0	-14.2, 17.5	-14.6, 22.8	-10.8, 31.8	-11.3, 25.5
Min, Max	-49.5, 149.4	-35.8, 195.8	-49.5, 195.8	-37.1, 149.4	-37.1, 195.8
SPV at Week 24 in Extended Treatment Phase					
N	30	17	47		
Mean (SD)	1868.7 (1118.83)	1868.8 (1063.82)	1868.7 (1087.57)		
Median	1703.9	1872.0	1793.7		
Q1, Q3	946.8, 2530.6	862.9, 2373.4	909.3, 2530.6		
Min, Max	193.3, 4677.4	624.4, 4329.9	193.3, 4677.4		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (BAT->MMB) group, the baseline is the last assessment prior to or on the date of the 1st dose of MMB in the ET phase.
For Continuing (MMB->MMB) group, the baseline is the last assessment prior to or on the date of randomization.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-spv-ext.sas V.03.05 Output file: t-chg-spv-ext.pdf 24AUG2023:15:00

**Table 2.1201: Analysis of Spleen Volume and % Change from Baseline
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set**

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=43)	Switch (BAT -> MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Percent of SPV Change from Baseline at Week 24 in Extended Treatment Phase					
N	30	17	47		
Mean (SD)	-10.7 (28.64)	-3.5 (30.14)	-8.1 (29.07)		
Median	-12.1	-2.0	-7.3		
Q1, Q3	-27.4, 11.9	-26.2, 12.6	-27.4, 12.6		
Min, Max	-63.3, 53.8	-44.4, 61.8	-63.3, 61.8		
SPV at Week 12 in Extended Treatment Phase					
N	33	19	52		
Mean (SD)	1983.1 (1290.10)	1970.8 (933.69)	1978.6 (1162.77)		
Median	1931.0	2085.7	1994.5		
Q1, Q3	1043.3, 2458.0	1087.8, 2501.5	1065.6, 2479.7		
Min, Max	168.5, 6122.2	593.2, 4287.7	168.5, 6122.2		
Percent of SPV Change from Baseline at Week 12 in Extended Treatment Phase					
N	33	19	52		
Mean (SD)	-6.2 (30.67)	-8.0 (15.29)	-6.9 (25.95)		
Median	-7.1	-8.0	-7.5		
Q1, Q3	-26.4, 15.2	-18.4, 5.5	-21.0, 10.5		
Min, Max	-63.9, 74.4	-38.3, 12.8	-63.9, 74.4		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (BAT->MMB) group, the baseline is the last assessment prior to or on the date of the 1st dose of MMB in the ET phase.
For Continuing (MMB->MMB) group, the baseline is the last assessment prior to or on the date of randomization.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-spv-ext.sas V.03.05 Output file: t-chg-spv-ext.pdf 24AUG2023:15:00

**Table 2.1201: Analysis of Spleen Volume and % Change from Baseline
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set**

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=43)	Switch (BAT -> MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
SPV at Week 36 in Extended Treatment Phase					
N	24	16	40		
Mean (SD)	1770.0 (1097.29)	1582.1 (828.42)	1694.8 (991.32)		
Median	1509.6	1609.4	1552.9		
Q1, Q3	1008.1, 2468.5	795.5, 2069.6	880.0, 2240.1		
Min, Max	198.1, 4805.7	443.4, 3057.5	198.1, 4805.7		
Percent of SPV Change from Baseline at Week 36 in Extended Treatment Phase					
N	24	16	40		
Mean (SD)	-10.9 (33.06)	-9.0 (42.77)	-10.1 (36.73)		
Median	-10.0	-18.1	-13.7		
Q1, Q3	-36.2, 14.6	-39.5, 4.5	-39.5, 12.2		
Min, Max	-63.0, 62.2	-60.5, 118.0	-63.0, 118.0		
SPV at Week 48 in Extended Treatment Phase					
N	23	15	38		
Mean (SD)	1723.2 (910.49)	1573.7 (945.07)	1664.2 (914.52)		
Median	1674.5	1547.6	1563.7		
Q1, Q3	938.7, 2297.8	700.3, 2168.0	878.1, 2276.6		
Min, Max	169.1, 3452.8	426.1, 3388.9	169.1, 3452.8		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (BAT->MMB) group, the baseline is the last assessment prior to or on the date of the 1st dose of MMB in the ET phase.
For Continuing (MMB->MMB) group, the baseline is the last assessment prior to or on the date of randomization.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-spv-ext.sas V.03.05 Output file: t-chg-spv-ext.pdf 24AUG2023:15:00

**Table 2.1201: Analysis of Spleen Volume and % Change from Baseline
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set**

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=43)	Switch (BAT -> MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Percent of SPV Change from Baseline at Week 48 in Extended Treatment Phase					
N	23	15	38		
Mean (SD)	-3.5 (36.16)	-9.5 (35.83)	-5.9 (35.67)		
Median	-13.5	1.8	-10.5		
Q1, Q3	-27.4, 25.5	-39.3, 11.1	-28.1, 14.8		
Min, Max	-56.9, 65.2	-62.1, 72.2	-62.1, 72.2		
SPV at Week 60 in Extended Treatment Phase					
N	19	13	32		
Mean (SD)	1854.4 (929.51)	1741.7 (779.29)	1808.6 (860.18)		
Median	1790.3	1867.5	1828.9		
Q1, Q3	1026.6, 2515.0	1526.2, 1986.0	1072.8, 2362.8		
Min, Max	430.8, 3535.0	446.9, 3247.2	430.8, 3535.0		
Percent of SPV Change from Baseline at Week 60 in Extended Treatment Phase					
N	19	13	32		
Mean (SD)	2.0 (39.87)	0.4 (64.35)	1.4 (50.27)		
Median	-6.1	-9.8	-8.9		
Q1, Q3	-30.9, 31.1	-36.2, 10.4	-33.9, 17.7		
Min, Max	-52.5, 82.5	-60.2, 195.8	-60.2, 195.8		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (BAT->MMB) group, the baseline is the last assessment prior to or on the date of the 1st dose of MMB in the ET phase.
For Continuing (MMB->MMB) group, the baseline is the last assessment prior to or on the date of randomization.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-spv-ext.sas V.03.05 Output file: t-chg-spv-ext.pdf 24AUG2023:15:00

**Table 2.1201: Analysis of Spleen Volume and % Change from Baseline
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set**

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=43)	Switch (BAT -> MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
SPV at Week 72 in Extended Treatment Phase					
N	14	11	25		
Mean (SD)	1776.6 (980.57)	1572.7 (756.25)	1686.9 (877.38)		
Median	1744.3	1883.0	1836.2		
Q1, Q3	1038.4, 2490.0	637.4, 1941.5	1038.4, 2128.8		
Min, Max	439.5, 3676.2	353.9, 2597.1	353.9, 3676.2		
Percent of SPV Change from Baseline at Week 72 in Extended Treatment Phase					
N	14	11	25		
Mean (SD)	-1.0 (35.24)	-21.9 (32.70)	-10.2 (35.08)		
Median	-9.4	-27.3	-11.1		
Q1, Q3	-29.5, 15.4	-52.7, -1.6	-37.1, 3.8		
Min, Max	-43.5, 63.0	-68.5, 33.6	-68.5, 63.0		
SPV at Week 84 in Extended Treatment Phase					
N	13	7	20		
Mean (SD)	1635.4 (897.34)	1645.0 (891.60)	1638.8 (871.57)		
Median	1611.8	1847.3	1729.5		
Q1, Q3	910.5, 2192.7	580.8, 2283.0	829.4, 2237.8		
Min, Max	459.7, 3475.1	406.7, 2902.7	406.7, 3475.1		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (BAT->MMB) group, the baseline is the last assessment prior to or on the date of the 1st dose of MMB in the ET phase.
For Continuing (MMB->MMB) group, the baseline is the last assessment prior to or on the date of randomization.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-spv-ext.sas V.03.05 Output file: t-chg-spv-ext.pdf 24AUG2023:15:00

**Table 2.1201: Analysis of Spleen Volume and % Change from Baseline
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set**

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=43)	Switch (BAT -> MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Percent of SPV Change from Baseline at Week 84 in Extended Treatment Phase					
N	13	7	20		
Mean (SD)	2.5 (48.32)	-22.8 (29.12)	-6.3 (43.54)		
Median	-9.9	-12.8	-12.4		
Q1, Q3	-28.1, 21.6	-52.5, 2.8	-36.3, 16.9		
Min, Max	-56.9, 108.4	-63.8, 15.5	-63.8, 108.4		
SPV at Week 96 in Extended Treatment Phase					
N	8	9	17		
Mean (SD)	1727.3 (834.01)	1586.4 (921.97)	1652.7 (857.08)		
Median	1653.8	1914.4	1914.4		
Q1, Q3	958.2, 2433.3	571.2, 2201.5	909.1, 2208.2		
Min, Max	846.0, 2882.0	360.1, 2941.5	360.1, 2941.5		
Percent of SPV Change from Baseline at Week 96 in Extended Treatment Phase					
N	8	9	17		
Mean (SD)	2.1 (62.51)	-24.3 (30.79)	-11.9 (48.66)		
Median	-14.8	-11.6	-11.6		
Q1, Q3	-43.7, 27.5	-53.3, -0.8	-45.2, -0.8		
Min, Max	-51.3, 129.9	-68.0, 11.4	-68.0, 129.9		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (BAT->MMB) group, the baseline is the last assessment prior to or on the date of the 1st dose of MMB in the ET phase.
For Continuing (MMB->MMB) group, the baseline is the last assessment prior to or on the date of randomization.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-spv-ext.sas V.03.05 Output file: t-chg-spv-ext.pdf 24AUG2023:15:00

**Table 2.1201: Analysis of Spleen Volume and % Change from Baseline
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set**

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=43)	Switch (BAT -> MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
SPV at Week 108 in Extended Treatment Phase					
N	7	9	16		
Mean (SD)	1773.2 (951.15)	1546.9 (922.39)	1645.9 (910.54)		
Median	1582.4	1694.8	1638.6		
Q1, Q3	941.8, 2883.2	489.3, 2258.4	854.8, 2332.6		
Min, Max	767.8, 3031.0	275.6, 2624.2	275.6, 3031.0		
Percent of SPV Change from Baseline at Week 108 in Extended Treatment Phase					
N	7	9	16		
Mean (SD)	32.7 (71.98)	-26.8 (32.97)	-0.8 (59.85)		
Median	38.6	-21.1	-16.8		
Q1, Q3	-38.7, 77.3	-62.8, -2.7	-43.8, 25.4		
Min, Max	-48.8, 149.4	-75.5, 12.2	-75.5, 149.4		
SPV at Week 120 in Extended Treatment Phase					
N	5	5	10		
Mean (SD)	1853.4 (663.36)	1338.2 (844.50)	1595.8 (765.68)		
Median	1915.9	1729.7	1850.1		
Q1, Q3	1784.4, 2013.7	557.2, 2048.5	850.8, 2048.5		
Min, Max	850.8, 2702.3	302.2, 2053.5	302.2, 2702.3		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (BAT->MMB) group, the baseline is the last assessment prior to or on the date of the 1st dose of MMB in the ET phase.
For Continuing (MMB->MMB) group, the baseline is the last assessment prior to or on the date of randomization.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-spv-ext.sas V.03.05 Output file: t-chg-spv-ext.pdf 24AUG2023:15:00

**Table 2.1201: Analysis of Spleen Volume and % Change from Baseline
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set**

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=43)	Switch (BAT -> MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Percent of SPV Change from Baseline at Week 120 in Extended Treatment Phase					
N	5	5	10		
Mean (SD)	1.3 (48.98)	-34.4 (31.40)	-16.6 (43.12)		
Median	-20.4	-29.3	-22.9		
Q1, Q3	-25.4, 49.8	-58.7, -14.8	-53.7, 3.6		
Min, Max	-53.7, 56.3	-73.1, 3.6	-73.1, 56.3		
SPV at Week 132 in Extended Treatment Phase					
N	3	5	8		
Mean (SD)	2009.8 (133.67)	1474.9 (980.98)	1675.5 (794.77)		
Median	2057.9	2058.4	2058.2		
Q1, Q3	1858.8, 2112.8	544.7, 2144.5	1201.7, 2128.6		
Min, Max	1858.8, 2112.8	278.3, 2348.6	278.3, 2348.6		
Percent of SPV Change from Baseline at Week 132 in Extended Treatment Phase					
N	3	5	8		
Mean (SD)	8.8 (46.89)	-28.8 (37.08)	-14.7 (42.35)		
Median	-14.5	-19.1	-16.8		
Q1, Q3	-21.8, 62.8	-59.6, 1.4	-40.7, 4.9		
Min, Max	-21.8, 62.8	-75.2, 8.5	-75.2, 62.8		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (BAT->MMB) group, the baseline is the last assessment prior to or on the date of the 1st dose of MMB in the ET phase.
For Continuing (MMB->MMB) group, the baseline is the last assessment prior to or on the date of randomization.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-spv-ext.sas V.03.05 Output file: t-chg-spv-ext.pdf 24AUG2023:15:00

**Table 2.1201: Analysis of Spleen Volume and % Change from Baseline
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set**

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=43)	Switch (BAT -> MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
SPV at Week 144 in Extended Treatment Phase					
N	2	2	4		
Mean (SD)	1392.7 (904.77)	2357.4 (50.74)	1875.1 (764.17)		
Median	1392.7	2357.4	2177.0		
Q1, Q3	753.0, 2032.5	2321.6, 2393.3	1392.7, 2357.4		
Min, Max	753.0, 2032.5	2321.6, 2393.3	753.0, 2393.3		
Percent of SPV Change from Baseline at Week 144 in Extended Treatment Phase					
N	2	2	4		
Mean (SD)	24.5 (69.70)	-0.1 (24.79)	12.2 (45.01)		
Median	24.5	-0.1	-0.1		
Q1, Q3	-24.8, 73.8	-17.6, 17.5	-21.2, 45.6		
Min, Max	-24.8, 73.8	-17.6, 17.5	-24.8, 73.8		
SPV at Week 156 in Extended Treatment Phase					
N	0	1	1		
Mean (SD)		2711.9	2711.9		
Median		2711.9	2711.9		
Q1, Q3		2711.9, 2711.9	2711.9, 2711.9		
Min, Max		2711.9, 2711.9	2711.9, 2711.9		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (BAT->MMB) group, the baseline is the last assessment prior to or on the date of the 1st dose of MMB in the ET phase.
For Continuing (MMB->MMB) group, the baseline is the last assessment prior to or on the date of randomization.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-spv-ext.sas V.03.05 Output file: t-chg-spv-ext.pdf 24AUG2023:15:00

**Table 2.1201: Analysis of Spleen Volume and % Change from Baseline
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set**

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=43)	Switch (BAT -> MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Percent of SPV Change from Baseline at Week 156 in Extended Treatment Phase					
N	0	1	1		
Mean (SD)		-6.6	-6.6		
Median		-6.6	-6.6		
Q1, Q3		-6.6, -6.6	-6.6, -6.6		
Min, Max		-6.6, -6.6	-6.6, -6.6		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (BAT->MMB) group, the baseline is the last assessment prior to or on the date of the 1st dose of MMB in the ET phase.
For Continuing (MMB->MMB) group, the baseline is the last assessment prior to or on the date of randomization.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-spv-ext.sas V.03.05 Output file: t-chg-spv-ext.pdf 24AUG2023:15:00

Table 2.1301: Analysis of Spleen Volume and % Change from Baseline
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=43)	Switch (BAT -> MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Spleen Volume at Baseline(cm^3)					
N	43	30	73	66	96
Mean (SD)	2333.5 (1300.53)	2069.6 (933.31)	2225.1 (1163.86)	2625.5 (1467.27)	2451.8 (1343.88)
Median	2357.6	2005.5	2049.3	2576.8	2317.2
Q1, Q3	1329.8, 3073.5	1289.3, 2723.4	1329.8, 2857.6	1340.9, 3541.6	1335.3, 3106.8
Min, Max	392.4, 6740.4	458.3, 4822.0	392.4, 6740.4	392.4, 6740.4	392.4, 6740.4
Minimum SPV in the Postbaseline Treatment Period					
N	38	25	63	56	81
Mean (SD)	1949.4 (1134.38)	1690.3 (1025.03)	1846.6 (1091.33)	2280.0 (1515.09)	2098.0 (1403.03)
Median	1909.9	1743.1	1852.8	1896.6	1847.3
Q1, Q3	929.8, 2516.7	721.0, 2417.9	909.1, 2458.0	968.9, 3227.7	947.7, 2826.4
Min, Max	168.5, 4677.4	275.6, 4287.7	168.5, 4677.4	168.5, 6072.8	168.5, 6072.8
Percent of Minimum SPV Change from Baseline in the Postbaseline Treatment Period					
N	38	25	63	56	81
Mean (SD)	-9.4 (32.26)	-18.3 (27.28)	-12.9 (30.47)	-10.1 (26.39)	-12.6 (26.77)
Median	-14.4	-19.9	-15.6	-10.6	-11.8
Q1, Q3	-28.1, 11.9	-32.9, -0.3	-32.5, 10.0	-28.3, 6.5	-31.1, 5.6
Min, Max	-63.9, 74.4	-72.6, 26.7	-72.6, 74.4	-63.9, 47.4	-72.6, 47.4

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Baseline is the last assessment prior to or on the date of randomization.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-spv-new.sas V.03.05 Output file: t-chg-spv-new.pdf 24AUG2023:15:00

Table 2.1301: Analysis of Spleen Volume and % Change from Baseline
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=43)	Switch (BAT -> MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Maximum SPV in the Postbaseline Treatment Period					
N	38	25	63	56	81
Mean (SD)	2344.3 (1233.69)	2132.5 (1089.10)	2260.2 (1174.03)	2706.5 (1509.95)	2529.3 (1412.26)
Median	2403.6	2127.8	2321.6	2581.6	2362.7
Q1, Q3	1313.6, 3031.0	1087.8, 2711.9	1224.3, 3001.7	1466.4, 3565.7	1395.6, 3247.2
Min, Max	198.1, 6122.2	448.6, 4329.9	198.1, 6122.2	268.2, 6122.2	268.2, 6122.2
Percent of Maximum SPV Change from Baseline in the Postbaseline Treatment Period					
N	38	25	63	56	81
Mean (SD)	12.4 (41.98)	6.6 (27.44)	10.1 (36.76)	12.8 (35.74)	10.9 (33.36)
Median	2.0	-2.1	0.7	3.6	1.2
Q1, Q3	-14.6, 32.0	-19.9, 26.7	-17.8, 28.5	-10.8, 31.8	-11.8, 28.8
Min, Max	-49.5, 149.4	-34.5, 79.4	-49.5, 149.4	-37.1, 149.4	-37.1, 149.4
SPV at Week 24 in Extended Treatment Phase					
N	30	17	47		
Mean (SD)	1868.7 (1118.83)	1868.8 (1063.82)	1868.7 (1087.57)		
Median	1703.9	1872.0	1793.7		
Q1, Q3	946.8, 2530.6	862.9, 2373.4	909.3, 2530.6		
Min, Max	193.3, 4677.4	624.4, 4329.9	193.3, 4677.4		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Baseline is the last assessment prior to or on the date of randomization.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-spv-new.sas V.03.05 Output file: t-chg-spv-new.pdf 24AUG2023:15:00

**Table 2.1301: Analysis of Spleen Volume and % Change from Baseline
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set**

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=43)	Switch (BAT -> MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Percent of SPV Change from Baseline at Week 24 in Extended Treatment Phase					
N	30	17	47		
Mean (SD)	-10.7 (28.64)	-7.8 (26.66)	-9.6 (27.68)		
Median	-12.1	-14.2	-13.1		
Q1, Q3	-27.4, 11.9	-29.5, 13.6	-29.5, 12.8		
Min, Max	-63.3, 53.8	-41.1, 39.6	-63.3, 53.8		
SPV at Week 12 in Extended Treatment Phase					
N	33	19	52		
Mean (SD)	1983.1 (1290.10)	1970.8 (933.69)	1978.6 (1162.77)		
Median	1931.0	2085.7	1994.5		
Q1, Q3	1043.3, 2458.0	1087.8, 2501.5	1065.6, 2479.7		
Min, Max	168.5, 6122.2	593.2, 4287.7	168.5, 6122.2		
Percent of SPV Change from Baseline at Week 12 in Extended Treatment Phase					
N	33	19	52		
Mean (SD)	-6.2 (30.67)	-9.0 (16.92)	-7.2 (26.33)		
Median	-7.1	-8.3	-8.3		
Q1, Q3	-26.4, 15.2	-22.0, 7.4	-22.9, 11.8		
Min, Max	-63.9, 74.4	-36.1, 22.6	-63.9, 74.4		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Baseline is the last assessment prior to or on the date of randomization.

Data Extracted: CRF data: 25JUN2019

**Table 2.1301: Analysis of Spleen Volume and % Change from Baseline
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set**

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=43)	Switch (BAT -> MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
SPV at Week 36 in Extended Treatment Phase					
N	24	16	40		
Mean (SD)	1770.0 (1097.29)	1582.1 (828.42)	1694.8 (991.32)		
Median	1509.6	1609.4	1552.9		
Q1, Q3	1008.1, 2468.5	795.5, 2069.6	880.0, 2240.1		
Min, Max	198.1, 4805.7	443.4, 3057.5	198.1, 4805.7		
Percent of SPV Change from Baseline at Week 36 in Extended Treatment Phase					
N	24	16	40		
Mean (SD)	-10.9 (33.06)	-14.5 (29.31)	-12.3 (31.27)		
Median	-10.0	-26.2	-19.8		
Q1, Q3	-36.2, 14.6	-32.8, 17.2	-32.8, 14.6		
Min, Max	-63.0, 62.2	-56.0, 32.3	-63.0, 62.2		
SPV at Week 48 in Extended Treatment Phase					
N	23	15	38		
Mean (SD)	1723.2 (910.49)	1573.7 (945.07)	1664.2 (914.52)		
Median	1674.5	1547.6	1563.7		
Q1, Q3	938.7, 2297.8	700.3, 2168.0	878.1, 2276.6		
Min, Max	169.1, 3452.8	426.1, 3388.9	169.1, 3452.8		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Baseline is the last assessment prior to or on the date of randomization.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-spv-new.sas V.03.05 Output file: t-chg-spv-new.pdf 24AUG2023:15:00

**Table 2.1301: Analysis of Spleen Volume and % Change from Baseline
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set**

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=43)	Switch (BAT -> MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Percent of SPV Change from Baseline at Week 48 in Extended Treatment Phase					
N	23	15	38		
Mean (SD)	-3.5 (36.16)	-14.9 (29.30)	-8.0 (33.68)		
Median	-13.5	-20.5	-14.2		
Q1, Q3	-27.4, 25.5	-40.2, 4.5	-28.6, 17.6		
Min, Max	-56.9, 65.2	-57.7, 39.8	-57.7, 65.2		
SPV at Week 60 in Extended Treatment Phase					
N	19	13	32		
Mean (SD)	1854.4 (929.51)	1741.7 (779.29)	1808.6 (860.18)		
Median	1790.3	1867.5	1828.9		
Q1, Q3	1026.6, 2515.0	1526.2, 1986.0	1072.8, 2362.8		
Min, Max	430.8, 3535.0	446.9, 3247.2	430.8, 3535.0		
Percent of SPV Change from Baseline at Week 60 in Extended Treatment Phase					
N	19	13	32		
Mean (SD)	2.0 (39.87)	-8.8 (39.53)	-2.4 (39.46)		
Median	-6.1	-24.8	-14.9		
Q1, Q3	-30.9, 31.1	-36.0, 23.5	-33.5, 25.3		
Min, Max	-52.5, 82.5	-55.6, 79.4	-55.6, 82.5		

**ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Baseline is the last assessment prior to or on the date of randomization.**

Data Extracted: CRF data: 25JUN2019

**Table 2.1301: Analysis of Spleen Volume and % Change from Baseline
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set**

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=43)	Switch (BAT -> MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
SPV at Week 72 in Extended Treatment Phase					
N	14	11	25		
Mean (SD)	1776.6 (980.57)	1572.7 (756.25)	1686.9 (877.38)		
Median	1744.3	1883.0	1836.2		
Q1, Q3	1038.4, 2490.0	637.4, 1941.5	1038.4, 2128.8		
Min, Max	439.5, 3676.2	353.9, 2597.1	353.9, 3676.2		
Percent of SPV Change from Baseline at Week 72 in Extended Treatment Phase					
N	14	11	25		
Mean (SD)	-1.0 (35.24)	-25.1 (28.99)	-11.6 (34.25)		
Median	-9.4	-30.7	-12.9		
Q1, Q3	-29.5, 15.4	-53.4, -1.5	-37.1, 3.8		
Min, Max	-43.5, 63.0	-64.9, 28.5	-64.9, 63.0		
SPV at Week 84 in Extended Treatment Phase					
N	13	7	20		
Mean (SD)	1635.4 (897.34)	1645.0 (891.60)	1638.8 (871.57)		
Median	1611.8	1847.3	1729.5		
Q1, Q3	910.5, 2192.7	580.8, 2283.0	829.4, 2237.8		
Min, Max	459.7, 3475.1	406.7, 2902.7	406.7, 3475.1		

**ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Baseline is the last assessment prior to or on the date of randomization.**

Table 2.1301: Analysis of Spleen Volume and % Change from Baseline
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=43)	Switch (BAT -> MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Percent of SPV Change from Baseline at Week 84 in Extended Treatment Phase					
N	13	7	20		
Mean (SD)	2.5 (48.32)	-27.1 (29.16)	-7.8 (44.20)		
Median	-9.9	-27.6	-19.9		
Q1, Q3	-28.1, 21.6	-51.6, -19.4	-38.4, 19.9		
Min, Max	-56.9, 108.4	-59.6, 29.1	-59.6, 108.4		
SPV at Week 96 in Extended Treatment Phase					
N	8	9	17		
Mean (SD)	1727.3 (834.01)	1586.4 (921.97)	1652.7 (857.08)		
Median	1653.8	1914.4	1914.4		
Q1, Q3	958.2, 2433.3	571.2, 2201.5	909.1, 2208.2		
Min, Max	846.0, 2882.0	360.1, 2941.5	360.1, 2941.5		
Percent of SPV Change from Baseline at Week 96 in Extended Treatment Phase					
N	8	9	17		
Mean (SD)	2.1 (62.51)	-28.2 (29.58)	-14.0 (48.89)		
Median	-14.8	-28.3	-18.4		
Q1, Q3	-43.7, 27.5	-52.4, -11.2	-45.2, -4.7		
Min, Max	-51.3, 129.9	-64.2, 24.5	-64.2, 129.9		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Baseline is the last assessment prior to or on the date of randomization.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-spv-new.sas V.03.05 Output file: t-chg-spv-new.pdf 24AUG2023:15:00

**Table 2.1301: Analysis of Spleen Volume and % Change from Baseline
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set**

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=43)	Switch (BAT -> MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
SPV at Week 108 in Extended Treatment Phase					
N	7	9	16		
Mean (SD)	1773.2 (951.15)	1546.9 (922.39)	1645.9 (910.54)		
Median	1582.4	1694.8	1638.6		
Q1, Q3	941.8, 2883.2	489.3, 2258.4	854.8, 2332.6		
Min, Max	767.8, 3031.0	275.6, 2624.2	275.6, 3031.0		
Percent of SPV Change from Baseline at Week 108 in Extended Treatment Phase					
N	7	9	16		
Mean (SD)	32.7 (71.98)	-31.0 (31.06)	-3.2 (60.44)		
Median	38.6	-27.2	-21.4		
Q1, Q3	-38.7, 77.3	-62.0, -18.2	-43.8, 32.0		
Min, Max	-48.8, 149.4	-72.6, 25.4	-72.6, 149.4		
SPV at Week 120 in Extended Treatment Phase					
N	5	5	10		
Mean (SD)	1853.4 (663.36)	1338.2 (844.50)	1595.8 (765.68)		
Median	1915.9	1729.7	1850.1		
Q1, Q3	1784.4, 2013.7	557.2, 2048.5	850.8, 2048.5		
Min, Max	850.8, 2702.3	302.2, 2053.5	302.2, 2702.3		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Baseline is the last assessment prior to or on the date of randomization.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-spv-new.sas V.03.05 Output file: t-chg-spv-new.pdf 24AUG2023:15:00

**Table 2.1301: Analysis of Spleen Volume and % Change from Baseline
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set**

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=43)	Switch (BAT -> MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Percent of SPV Change from Baseline at Week 120 in Extended Treatment Phase					
N	5	5	10		
Mean (SD)	1.3 (48.98)	-32.8 (34.35)	-15.7 (43.74)		
Median	-20.4	-33.9	-22.9		
Q1, Q3	-25.4, 49.8	-59.3, -16.5	-53.7, 15.9		
Min, Max	-53.7, 56.3	-70.0, 15.9	-70.0, 56.3		
SPV at Week 132 in Extended Treatment Phase					
N	3	5	8		
Mean (SD)	2009.8 (133.67)	1474.9 (980.98)	1675.5 (794.77)		
Median	2057.9	2058.4	2058.2		
Q1, Q3	1858.8, 2112.8	544.7, 2144.5	1201.7, 2128.6		
Min, Max	1858.8, 2112.8	278.3, 2348.6	278.3, 2348.6		
Percent of SPV Change from Baseline at Week 132 in Extended Treatment Phase					
N	3	5	8		
Mean (SD)	8.8 (46.89)	-27.3 (39.35)	-13.7 (43.16)		
Median	-14.5	-24.4	-18.1		
Q1, Q3	-21.8, 62.8	-60.2, -0.7	-42.3, 10.3		
Min, Max	-21.8, 62.8	-72.4, 21.3	-72.4, 62.8		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Baseline is the last assessment prior to or on the date of randomization.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-spv-new.sas V.03.05 Output file: t-chg-spv-new.pdf 24AUG2023:15:00

Table 2.1301: Analysis of Spleen Volume and % Change from Baseline
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=43)	Switch (BAT -> MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
SPV at Week 144 in Extended Treatment Phase					
N	2	2	4		
Mean (SD)	1392.7 (904.77)	2357.4 (50.74)	1875.1 (764.17)		
Median	1392.7	2357.4	2177.0		
Q1, Q3	753.0, 2032.5	2321.6, 2393.3	1392.7, 2357.4		
Min, Max	753.0, 2032.5	2321.6, 2393.3	753.0, 2393.3		
Percent of SPV Change from Baseline at Week 144 in Extended Treatment Phase					
N	2	2	4		
Mean (SD)	24.5 (69.70)	4.2 (38.34)	14.4 (47.41)		
Median	24.5	4.2	4.2		
Q1, Q3	-24.8, 73.8	-22.9, 31.3	-23.8, 52.6		
Min, Max	-24.8, 73.8	-22.9, 31.3	-24.8, 73.8		
SPV at Week 156 in Extended Treatment Phase					
N	0	1	1		
Mean (SD)		2711.9	2711.9		
Median		2711.9	2711.9		
Q1, Q3		2711.9, 2711.9	2711.9, 2711.9		
Min, Max		2711.9, 2711.9	2711.9, 2711.9		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Baseline is the last assessment prior to or on the date of randomization.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-spv-new.sas V.03.05 Output file: t-chg-spv-new.pdf 24AUG2023:15:00

**Table 2.1301: Analysis of Spleen Volume and % Change from Baseline
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set**

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB -> MMB) (N=43)	Switch (BAT -> MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Percent of SPV Change from Baseline at Week 156 in Extended Treatment Phase					
N	**0**	**1**	**1**		
Mean (SD)		**-12.7**	**-12.7**		
Median		**-12.7**	**-12.7**		
Q1, Q3		**-12.7, -12.7**	**-12.7, -12.7**		
Min, Max		**-12.7, -12.7**	**-12.7, -12.7**		

**ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Baseline is the last assessment prior to or on the date of randomization.**

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Table 2.1101: Analysis of Spleen Volume, Change and % Change from Baseline at Weeks 12 and 24
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Spleen Volume (cm^3) at Baseline		
n	66	39
Mean (SD)	2625.5 (1467.27)	2299.6 (1157.20)
Median	2576.8	2049.3
Q1, Q3	1340.9, 3541.6	1369.2, 2804.3
Min, Max	392.4, 6740.4	458.3, 5299.5
Spleen Volume (cm^3) at Week 12		
n	53	31
Mean (SD)	2460.9 (1558.95)	2077.7 (982.50)
Median	2172.6	1825.6
Q1, Q3	1205.1, 3486.9	1263.3, 2685.3
Min, Max	268.2, 6072.8	494.8, 4816.6
Change in Spleen Volume (cm^3) at Week 12 from Baseline		
n	53	31
Mean (SD)	-70.2 (581.66)	-37.2 (379.60)
Median	-58.6	29.6
Q1, Q3	-453.5, 302.8	-247.2, 145.7
Min, Max	-1295.8, 1455.2	-1017.9, 805.7

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.1101: Analysis of Spleen Volume, Change and % Change from Baseline at Weeks 12 and 24
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Change from Baseline at Week 12		
n [1]	56	33
n [2]	53	31
MMRM: Least Squares Mean [SE] (95% CI)	-85.82 [84.61] (-254.10, 82.46)	-49.47 [92.24] (-232.94, 133.99)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-36.35 [118.48] (-272.00, 199.31)	
MMRM: P-value	0.76	
Corrected Hedges' g (95% CI)	-0.062 (-0.505, 0.381)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.55	
Percent Change in Spleen Volume (cm^3) at Week 12 from Baseline		
n	53	31
Mean (SD)	-2.4 (24.18)	-0.2 (17.79)
Median	-5.3	1.3
Q1, Q3	-20.0, 13.5	-11.0, 11.2
Min, Max	-50.2, 47.4	-32.8, 39.3
Difference in Percent Change from Baseline at Week 12		
n [1]	56	33
n [2]	53	31
MMRM: Least Squares Mean [SE] (95% CI)	-3.02 [3.63] (-10.25, 4.21)	-0.46 [3.96] (-8.34, 7.43)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.56 [5.09] (-12.68, 7.56)	
MMRM: P-value	0.62	
Corrected Hedges' g (95% CI)	-0.102 (-0.545, 0.342)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.43	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.1101: Analysis of Spleen Volume, Change and % Change from Baseline at Weeks 12 and 24
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Spleen Volume (cm^3) at Week 24		
n	44	30
Mean (SD)	2137.4 (1288.00)	2131.7 (1057.11)
Median	2032.9	2021.2
Q1, Q3	1108.9, 2826.1	1224.0, 2804.8
Min, Max	228.2, 5774.1	429.6, 4999.9
Change in Spleen Volume (cm^3) at Week 24 from Baseline		
n	44	30
Mean (SD)	-95.3 (527.71)	79.9 (525.24)
Median	-82.5	5.8
Q1, Q3	-366.9, 211.8	-200.4, 256.6
Min, Max	-1537.9, 1309.1	-1084.0, 1720.5
Difference in Change from Baseline at Week 24		
n [1]	56	33
n [2]	44	30
MMRM: Least Squares Mean [SE] (95% CI)	-73.19 [93.71] (-259.58, 113.20)	58.65 [103.99] (-148.18, 265.48)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-131.84 [134.13] (-398.62, 134.93)	
MMRM: P-value	0.33	
Corrected Hedges' g (95% CI)	-0.217 (-0.682, 0.248)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.28	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.1101: Analysis of Spleen Volume, Change and % Change from Baseline at Weeks 12 and 24
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Spleen Volume (cm^3) at Week 24 from Baseline		
n	44	30
Mean (SD)	-4.9 (25.04)	3.5 (26.32)
Median	-2.9	0.8
Q1, Q3	-24.1, 8.9	-8.1, 14.4
Min, Max	-51.6, 49.8	-48.9, 87.0
Difference in Percent Change from Baseline at Week 24		
n [1]	56	33
n [2]	44	30
MMRM: Least Squares Mean [SE] (95% CI)	-3.23 [4.25] (-11.69, 5.23)	2.76 [4.78] (-6.74, 12.27)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-5.99 [6.16] (-18.25, 6.26)	
MMRM: P-value	0.33	
Corrected Hedges' g (95% CI)	-0.216 (-0.682, 0.249)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.24	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

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Table 2.0802: Analysis of Duration of MRI/CT Splenic Response by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Subjects with Event					
Loss of spleen response, n(%)	0	0	0	0	
Censor					
Subjects Censored, n(%)	24 (100.0%)	9 (100.0%)	42 (100.0%)	30 (100.0%)	
Non-Responder: Censored at Randomization Date	23 (95.8%)	9 (100.0%)	37 (88.1%)	28 (93.3%)	
No Loss of Response: Censored at Last MRI Spleen Assessment Date in RT phase (including up to 10 days after First Dose Date of ET phase)	1 (4.2%)	0	5 (11.9%)	2 (6.7%)	
Kaplan-Meier Estimate of Duration of Spleen Response (Weeks)					
25-percentile (95% CI)	NA	NA	NA	NA	
Median (95% CI)	NA	NA	NA	NA	
75-percentile (95% CI)	NA	NA	NA	NA	
Min, Max	0.14, 0.14	0.14, 0.14	0.14, 12.14	0.14, 0.14	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction.
MRI = Magnetic Resonance Imaging. CT = Computerized Tomography.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-sr-sub.sas V.03.05 Output file: t-dur-sr-age.pdf 24AUG2023:16:31

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Table 2.0806: Analysis of Duration of MRI/CT Splenic Response by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Subjects with Event					
Loss of spleen response, n(%)	0	0	0	0	
Censor					
Subjects Censored, n(%)	49 (100.0%)	31 (100.0%)	17 (100.0%)	8 (100.0%)	
Non-Responder: Censored at Randomization Date	44 (89.8%)	29 (93.5%)	16 (94.1%)	8 (100.0%)	
No Loss of Response: Censored at Last MRI Spleen Assessment Date in RT phase (including up to 10 days after First Dose Date of ET phase)	5 (10.2%)	2 (6.5%)	1 (5.9%)	0	
Kaplan-Meier Estimate of Duration of Spleen Response (Weeks)					
25-percentile (95% CI)	NA	NA	NA	NA	
Median (95% CI)	NA	NA	NA	NA	
75-percentile (95% CI)	NA	NA	NA	NA	
Min, Max	0.14, 12.14	0.14, 0.14	0.14, 0.14	0.14, 0.14	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction.
MRI = Magnetic Resonance Imaging. CT = Computerized Tomography.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-sr-sub.sas V.03.05 Output file: t-dur-sr-dipss2.pdf 24AUG2023:16:32

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Table 2.0805: Analysis of Duration of MRI/CT Splenic Response by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Subjects with Event				
Loss of spleen response, n(%)	0	0	0	0
Censor				
Subjects Censored, n(%)	5 (100.0%)	7 (100.0%)	44 (100.0%)	24 (100.0%)
Non-Responder: Censored at Randomization Date	4 (80.0%)	7 (100.0%)	40 (90.9%)	22 (91.7%)
No Loss of Response: Censored at Last MRI Spleen Assessment Date in RT phase (including up to 10 days after First Dose Date of ET phase)	1 (20.0%)	0	4 (9.1%)	2 (8.3%)
Kaplan-Meier Estimate of Duration of Spleen Response (Weeks)				
25-percentile (95% CI)	NA	NA	NA	NA
Median (95% CI)	NA	NA	NA	NA
75-percentile (95% CI)	NA	NA	NA	NA
Min, Max	0.14, 0.14	0.14, 0.14	0.14, 12.14	0.14, 0.14
Stratified Log-Rank Test p-value	NA		NA	
Adjusted Hazard Ratio (95% CI)	NA		NA	
Unstratified Log-Rank Test p-value	NA		NA	
Unadjusted Hazard Ratio (95% CI)	NA		NA	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction.
MRI = Magnetic Resonance Imaging. CT = Computerized Tomography.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-sr-sub.sas V.03.05 Output file: t-dur-sr-dipss3.pdf 24AUG2023:16:32

Table 2.0805: Analysis of Duration of MRI/CT Splenic Response by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=17)	High Risk BAT (N=8)	p-value
Subjects with Event			
Loss of spleen response, n(%)	0	0	
Censor			
Subjects Censored, n(%)	17 (100.0%)	8 (100.0%)	
Non-Responder: Censored at Randomization Date	16 (94.1%)	8 (100.0%)	
No Loss of Response: Censored at Last MRI Spleen Assessment Date in RT phase (including up to 10 days after First Dose Date of ET phase)	1 (5.9%)	0	
Kaplan-Meier Estimate of Duration of Spleen Response (Weeks)			
25-percentile (95% CI)	NA	NA	
Median (95% CI)	NA	NA	
75-percentile (95% CI)	NA	NA	
Min, Max	0.14, 0.14	0.14, 0.14	
Stratified Log-Rank Test p-value	NA		
Adjusted Hazard Ratio (95% CI)	NA		
Unstratified Log-Rank Test p-value	NA		
Unadjusted Hazard Ratio (95% CI)	NA		
P-value for interaction test			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction.
MRI = Magnetic Resonance Imaging. CT = Computerized Tomography.
Data Extracted: CRF data: 25JUN2019
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Table 2.0804: Analysis of Duration of MRI/CT Splenic Response by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Subjects with Event					
Loss of spleen response, n(%)	0	0	0	0	
Censor					
Subjects Censored, n(%)	29 (100.0%)	7 (100.0%)	37 (100.0%)	32 (100.0%)	
Non-Responder: Censored at Randomization Date	25 (86.2%)	7 (100.0%)	35 (94.6%)	30 (93.8%)	
No Loss of Response: Censored at Last MRI Spleen Assessment Date in RT phase (including up to 10 days after First Dose Date of ET phase)	4 (13.8%)	0	2 (5.4%)	2 (6.3%)	
Kaplan-Meier Estimate of Duration of Spleen Response (Weeks)					
25-percentile (95% CI)	NA	NA	NA	NA	
Median (95% CI)	NA	NA	NA	NA	
75-percentile (95% CI)	NA	NA	NA	NA	
Min, Max	0.14, 11.14	0.14, 0.14	0.14, 12.14	0.14, 0.14	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction.
MRI = Magnetic Resonance Imaging. CT = Computerized Tomography.
Data Extracted: CRF data: 25JUN2019
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Table 2.0807: Analysis of Duration of MRI/CT Splenic Response by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Subjects with Event					
Loss of spleen response, n(%)	0	0	0	0	
Censor					
Subjects Censored, n(%)	27 (100.0%)	6 (100.0%)	39 (100.0%)	33 (100.0%)	
Non-Responder: Censored at Randomization Date	23 (85.2%)	6 (100.0%)	37 (94.9%)	31 (93.9%)	
No Loss of Response: Censored at Last MRI Spleen Assessment Date in RT phase (including up to 10 days after First Dose Date of ET phase)	4 (14.8%)	0	2 (5.1%)	2 (6.1%)	
Kaplan-Meier Estimate of Duration of Spleen Response (Weeks)					
25-percentile (95% CI)	NA	NA	NA	NA	
Median (95% CI)	NA	NA	NA	NA	
75-percentile (95% CI)	NA	NA	NA	NA	
Min, Max	0.14, 12.14	0.14, 0.14	0.14, 0.14	0.14, 0.14	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction.
MRI = Magnetic Resonance Imaging. CT = Computerized Tomography.
Data Extracted: CRF data: 25JUN2019
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Table 2.0808: Analysis of Duration of MRI/CT Splenic Response by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=13)	BAT (N=8)	MMB (N=8)	BAT (N=8)
Subjects with Event				
Loss of spleen response, n(%)	0	0	0	0
Censor				
Subjects Censored, n(%)	13 (100.0%)	8 (100.0%)	8 (100.0%)	8 (100.0%)
Non-Responder: Censored at Randomization Date	10 (76.9%)	8 (100.0%)	8 (100.0%)	7 (87.5%)
No Loss of Response: Censored at Last MRI Spleen Assessment Date in RT phase (including up to 10 days after First Dose Date of ET phase)	3 (23.1%)	0	0	1 (12.5%)
Kaplan-Meier Estimate of Duration of Spleen Response (Weeks)				
25-percentile (95% CI)	NA	NA	NA	NA
Median (95% CI)	NA	NA	NA	NA
75-percentile (95% CI)	NA	NA	NA	NA
Min, Max	0.14, 11.14	0.14, 0.14	0.14, 0.14	0.14, 0.14
Stratified Log-Rank Test p-value	NA		NA	
Adjusted Hazard Ratio (95% CI)	NA		NA	
Unstratified Log-Rank Test p-value	NA		NA	
Unadjusted Hazard Ratio (95% CI)	NA		NA	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction.
MRI = Magnetic Resonance Imaging. CT = Computerized Tomography.
Data Extracted: CRF data: 25JUN2019

Table 2.0808: Analysis of Duration of MRI/CT Splenic Response by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Primary Myelofibrosis MMB (N=45)	Primary Myelofibrosis BAT (N=23)	p-value
Subjects with Event			
Loss of spleen response, n(%)	0	0	
Censor			
Subjects Censored, n(%)	45 (100.0%)	23 (100.0%)	
Non-Responder: Censored at Randomization Date	42 (93.3%)	22 (95.7%)	
No Loss of Response: Censored at Last MRI Spleen Assessment Date in RT phase (including up to 10 days after First Dose Date of ET phase)	3 (6.7%)	1 (4.3%)	
Kaplan-Meier Estimate of Duration of Spleen Response (Weeks)			
25-percentile (95% CI)	NA	NA	
Median (95% CI)	NA	NA	
75-percentile (95% CI)	NA	NA	
Min, Max	0.14, 12.14	0.14, 0.14	
Stratified Log-Rank Test p-value	NA		
Adjusted Hazard Ratio (95% CI)	NA		
Unstratified Log-Rank Test p-value	NA		
Unadjusted Hazard Ratio (95% CI)	NA		
P-value for interaction test			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction.
MRI = Magnetic Resonance Imaging. CT = Computerized Tomography.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-sr-sub.sas V.03.05 Output file: t-dur-sr-mf.pdf 24AUG2023:16:32

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Table 2.0803: Analysis of Duration of MRI/CT Splenic Response by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Subjects with Event					
Loss of spleen response, n(%)	0	0	0	0	
Censor					
Subjects Censored, n(%)	52 (100.0%)	18 (100.0%)	14 (100.0%)	21 (100.0%)	
Non-Responder: Censored at Randomization Date	48 (92.3%)	17 (94.4%)	12 (85.7%)	20 (95.2%)	
No Loss of Response: Censored at Last MRI Spleen Assessment Date in RT phase (including up to 10 days after First Dose Date of ET phase)	4 (7.7%)	1 (5.6%)	2 (14.3%)	1 (4.8%)	
Kaplan-Meier Estimate of Duration of Spleen Response (Weeks)					
25-percentile (95% CI)	NA	NA	NA	NA	
Median (95% CI)	NA	NA	NA	NA	
75-percentile (95% CI)	NA	NA	NA	NA	
Min, Max	0.14, 12.14	0.14, 0.14	0.14, 10.57	0.14, 0.14	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction.
MRI = Magnetic Resonance Imaging. CT = Computerized Tomography.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-sr-sub.sas V.03.05 Output file: t-dur-sr-sex.pdf 24AUG2023:16:32

GSK Oncology

Study GS-US-352-1214

Table 2.0810: Analysis of Duration of MRI/CT Splenic Response by Baseline Spleen Volume

Randomized Treatment Phase

ITT-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Subjects with Event					
Loss of spleen response, n(%)	0	0	0	0	
Censor					
Subjects Censored, n(%)	28 (100.0%)	24 (100.0%)	38 (100.0%)	15 (100.0%)	
Non-Responder: Censored at Randomization Date	25 (89.3%)	22 (91.7%)	35 (92.1%)	15 (100.0%)	
No Loss of Response: Censored at Last MRI Spleen Assessment Date in RT phase (including up to 10 days after First Dose Date of ET phase)	3 (10.7%)	2 (8.3%)	3 (7.9%)	0	
Kaplan-Meier Estimate of Duration of Spleen Response (Weeks)					
25-percentile (95% CI)	NA	NA	NA	NA	
Median (95% CI)	NA	NA	NA	NA	
75-percentile (95% CI)	NA	NA	NA	NA	
Min, Max	0.14, 10.57	0.14, 0.14	0.14, 12.14	0.14, 0.14	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).

Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.

Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.

P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction.

MRI = Magnetic Resonance Imaging. CT = Computerized Tomography.

Data Extracted: CRF data: 25JUN2019

GSK Oncology
Study GS-US-352-1214

Table 2.0809: Analysis of Duration of MRI/CT Splenic Response by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Subjects with Event					
Loss of spleen response, n(%)	0	0	0	0	
Censor					
Subjects Censored, n(%)	42 (100.0%)	20 (100.0%)	24 (100.0%)	19 (100.0%)	
Non-Responder: Censored at Randomization Date	38 (90.5%)	18 (90.0%)	22 (91.7%)	19 (100.0%)	
No Loss of Response: Censored at Last MRI Spleen Assessment Date in RT phase (including up to 10 days after First Dose Date of ET phase)	4 (9.5%)	2 (10.0%)	2 (8.3%)	0	
Kaplan-Meier Estimate of Duration of Spleen Response (Weeks)					
25-percentile (95% CI)	NA	NA	NA	NA	
Median (95% CI)	NA	NA	NA	NA	
75-percentile (95% CI)	NA	NA	NA	NA	
Min, Max	0.14, 11.14	0.14, 0.14	0.14, 12.14	0.14, 0.14	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment and baseline TD (yes,no).
Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no) and treatment by subgroup interaction.
MRI = Magnetic Resonance Imaging. CT = Computerized Tomography.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-sr-sub.sas V.03.05 Output file: t-dur-sr-tss.pdf 24AUG2023:16:32

Table 2.0801: Analysis of Duration of MRI/CT Splenic Response
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Subjects with Event		
Loss of spleen response, n(%)	0	0
Censor		
Subjects Censored, n(%)	66 (100.0%)	39 (100.0%)
Non-Responder: Censored at Randomization Date	60 (90.9%)	37 (94.9%)
No Loss of Response: Censored at Last MRI Spleen Assessment Date in RT phase (including up to 10 days after First Dose Date of ET phase)	6 (9.1%)	2 (5.1%)
Kaplan-Meier Estimate of Duration of Spleen Response (Weeks)		
25-percentile (95% CI)	NA	NA
Median (95% CI)	NA	NA
75-percentile (95% CI)	NA	NA
Min, Max	0.14, 12.14	0.14, 0.14
Stratified Log-Rank Test p-value	NA	
Adjusted Hazard Ratio (95% CI)	NA	
Unstratified Log-Rank Test p-value	NA	
Unadjusted Hazard Ratio (95% CI)	NA	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
MRI = Magnetic Resonance Imaging. CT = Computerized Tomography.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-sr.sas V.03.05 Output file: t-dur-sr.pdf 24AUG2023:16:30

Table 2.0301: Analysis of Splenic Response
Extended Treatment Phase (Week 24 Onward) and Overall MMB Period
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Spleen Volume (cm^3) at Baseline					
N	43	30	73	66	96
Mean (SD)	2333.5 (1300.53)	2199.7 (1056.22)	2278.5 (1200.15)	2625.5 (1467.27)	2492.4 (1361.23)
Median	2357.6	2101.8	2173.3	2576.8	2425.6
Q1, Q3	1329.8, 3073.5	1237.6, 2904.8	1329.8, 3064.2	1340.9, 3541.6	1335.3, 3202.5
Min, Max	392, 6740	430, 5000	392, 6740	392, 6740	392, 6740
Splenic Response Rate at Any Timepoint of Overall Exposed to MMB Period					
Responder, n(%)				8 (12.1%)	15 (15.6%)
95% Exact CI				0.0538, 0.2249	0.0902, 0.2446
Splenic Response Rate at Any Timepoint of ET Phase					
Subjects Ongoing and not Reach the 1st Assessment Timepoint in ET Phase, n(%)	0	0	0		
Subjects Discontinued or Reached the 1st Assessment Timepoint in ET Phase, n(%)	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Responder, n(%)	7 (16.3%)	7 (23.3%)	14 (19.2%)		
95% Exact CI	0.0681, 0.3070	0.0993, 0.4228	0.1090, 0.3008		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
For Switch (BAT->MMB) group, the baseline is the last assessment prior to or on the date of the 1st dose of MMB in the ET phase.
For Continuing (MMB->MMB) group, the baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 25JUN2019

Table 2.0301: Analysis of Splenic Response
Extended Treatment Phase (Week 24 Onward) and Overall MMB Period
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Week 24 in ET Phase					
Subjects ongoing and not reaching week 24 in ET phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 24 in ET Phase	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Splenic Response Rate at Week 24 in ET Phase					
Responder, n(%)	7 (16.3%)	4 (13.3%)	11 (15.1%)		
95% Exact CI	0.0681, 0.3070	0.0376, 0.3072	0.0777, 0.2536		
Non-Responder, n(%)	36 (83.7%)	26 (86.7%)	62 (84.9%)		
Baseline spleen volume not available	0	0	0		
Spleen volume at week 24 not available	13 (30.2%)	13 (43.3%)	26 (35.6%)		
>0% spleen volume increase at week 24	10 (23.3%)	8 (26.7%)	18 (24.7%)		
<35% spleen volume reduction from baseline	23 (53.5%)	13 (43.3%)	36 (49.3%)		
Discontinuation early at week 24	9 (20.9%)	12 (40.0%)	21 (28.8%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
For Switch (BAT->MMB) group, the baseline is the last assessment prior to or on the date of the 1st dose of MMB in the ET phase.
For Continuing (MMB->MMB) group, the baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 25JUN2019

Table 2.0301: Analysis of Splenic Response
Extended Treatment Phase (Week 24 Onward) and Overall MMB Period
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Week 12 in ET Phase					
Subjects ongoing and not reaching week 12 in ET phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 12 in ET Phase	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Splenic Response Rate at Week 12 in ET Phase					
Responder, n(%)	5 (11.6%)	1 (3.3%)	6 (8.2%)		
95% Exact CI	0.0389, 0.2508	0.0008, 0.1722	0.0308, 0.1704		
Non-Responder, n(%)	38 (88.4%)	29 (96.7%)	67 (91.8%)		
Baseline spleen volume not available	0	0	0		
Spleen volume at week 12 not available	10 (23.3%)	11 (36.7%)	21 (28.8%)		
>0% spleen volume increase at week 12	13 (30.2%)	8 (26.7%)	21 (28.8%)		
<35% spleen volume reduction from baseline	28 (65.1%)	18 (60.0%)	46 (63.0%)		
Discontinuation early at week 12	1 (2.3%)	6 (20.0%)	7 (9.6%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
For Switch (BAT->MMB) group, the baseline is the last assessment prior to or on the date of the 1st dose of MMB in the ET phase.
For Continuing (MMB->MMB) group, the baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 25JUN2019

Table 2.0301: Analysis of Splenic Response
Extended Treatment Phase (Week 24 Onward) and Overall MMB Period
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Week 36 in ET Phase					
Subjects ongoing and not reaching week 36 in ET phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 36 in ET Phase	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Splenic Response Rate at Week 36 in ET Phase					
Responder, n(%)	6 (14.0%)	5 (16.7%)	11 (15.1%)		
95% Exact CI	0.0530, 0.2793	0.0564, 0.3472	0.0777, 0.2536		
Non-Responder, n(%)	37 (86.0%)	25 (83.3%)	62 (84.9%)		
Baseline spleen volume not available	0	0	0		
Spleen volume at week 36 not available	19 (44.2%)	14 (46.7%)	33 (45.2%)		
>0% spleen volume increase at week 36	9 (20.9%)	5 (16.7%)	14 (19.2%)		
<35% spleen volume reduction from baseline	18 (41.9%)	11 (36.7%)	29 (39.7%)		
Discontinuation early at week 36	11 (25.6%)	14 (46.7%)	25 (34.2%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
For Switch (BAT->MMB) group, the baseline is the last assessment prior to or on the date of the 1st dose of MMB in the ET phase.
For Continuing (MMB->MMB) group, the baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 25JUN2019

Table 2.0301: Analysis of Splenic Response
Extended Treatment Phase (Week 24 Onward) and Overall MMB Period
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Week 48 in ET Phase					
Subjects ongoing and not reaching week 48 in ET phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 48 in ET Phase	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Splenic Response Rate at Week 48 in ET Phase					
Responder, n(%)	4 (9.3%)	5 (16.7%)	9 (12.3%)		
95% Exact CI	0.0259, 0.2214	0.0564, 0.3472	0.0580, 0.2212		
Non-Responder, n(%)	39 (90.7%)	25 (83.3%)	64 (87.7%)		
Baseline spleen volume not available	0	0	0		
Spleen volume at week 48 not available	20 (46.5%)	15 (50.0%)	35 (47.9%)		
>0% spleen volume increase at week 48	8 (18.6%)	8 (26.7%)	16 (21.9%)		
<35% spleen volume reduction from baseline	19 (44.2%)	10 (33.3%)	29 (39.7%)		
Discontinuation early at week 48	18 (41.9%)	14 (46.7%)	32 (43.8%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
For Switch (BAT->MMB) group, the baseline is the last assessment prior to or on the date of the 1st dose of MMB in the ET phase.
For Continuing (MMB->MMB) group, the baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 25JUN2019

Table 2.0301: Analysis of Splenic Response
Extended Treatment Phase (Week 24 Onward) and Overall MMB Period
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Week 60 in ET Phase					
Subjects ongoing and not reaching week 60 in ET phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 60 in ET Phase	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Splenic Response Rate at Week 60 in ET Phase					
Responder, n(%)	4 (9.3%)	4 (13.3%)	8 (11.0%)		
95% Exact CI	0.0259, 0.2214	0.0376, 0.3072	0.0485, 0.2046		
Non-Responder, n(%)	39 (90.7%)	26 (86.7%)	65 (89.0%)		
Baseline spleen volume not available	0	0	0		
Spleen volume at week 60 not available	24 (55.8%)	17 (56.7%)	41 (56.2%)		
>0% spleen volume increase at week 60	8 (18.6%)	4 (13.3%)	12 (16.4%)		
<35% spleen volume reduction from baseline	15 (34.9%)	9 (30.0%)	24 (32.9%)		
Discontinuation early at week 60	22 (51.2%)	15 (50.0%)	37 (50.7%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
For Switch (BAT->MMB) group, the baseline is the last assessment prior to or on the date of the 1st dose of MMB in the ET phase.
For Continuing (MMB->MMB) group, the baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 25JUN2019

Table 2.0301: Analysis of Splenic Response
Extended Treatment Phase (Week 24 Onward) and Overall MMB Period
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Week 72 in ET Phase					
Subjects ongoing and not reaching week 72 in ET phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 72 in ET Phase	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Splenic Response Rate at Week 72 in ET Phase					
Responder, n(%)	3 (7.0%)	4 (13.3%)	7 (9.6%)		
95% Exact CI	0.0146, 0.1906	0.0376, 0.3072	0.0394, 0.1876		
Non-Responder, n(%)	40 (93.0%)	26 (86.7%)	66 (90.4%)		
Baseline spleen volume not available	0	0	0		
Spleen volume at week 72 not available	29 (67.4%)	19 (63.3%)	48 (65.8%)		
>0% spleen volume increase at week 72	6 (14.0%)	2 (6.7%)	8 (11.0%)		
<35% spleen volume reduction from baseline	11 (25.6%)	7 (23.3%)	18 (24.7%)		
Discontinuation early at week 72	25 (58.1%)	17 (56.7%)	42 (57.5%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
For Switch (BAT->MMB) group, the baseline is the last assessment prior to or on the date of the 1st dose of MMB in the ET phase.
For Continuing (MMB->MMB) group, the baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 25JUN2019

Table 2.0301: Analysis of Splenic Response
Extended Treatment Phase (Week 24 Onward) and Overall MMB Period
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Week 84 in ET Phase					
Subjects ongoing and not reaching week 84 in ET phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 84 in ET Phase	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Splenic Response Rate at Week 84 in ET Phase					
Responder, n(%)	3 (7.0%)	3 (10.0%)	6 (8.2%)		
95% Exact CI	0.0146, 0.1906	0.0211, 0.2653	0.0308, 0.1704		
Non-Responder, n(%)	40 (93.0%)	27 (90.0%)	67 (91.8%)		
Baseline spleen volume not available	0	0	0		
Spleen volume at week 84 not available	30 (69.8%)	23 (76.7%)	53 (72.6%)		
>0% spleen volume increase at week 84	5 (11.6%)	2 (6.7%)	7 (9.6%)		
<35% spleen volume reduction from baseline	10 (23.3%)	4 (13.3%)	14 (19.2%)		
Discontinuation early at week 84	27 (62.8%)	19 (63.3%)	46 (63.0%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
For Switch (BAT->MMB) group, the baseline is the last assessment prior to or on the date of the 1st dose of MMB in the ET phase.
For Continuing (MMB->MMB) group, the baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ext-sr-et.sas V.03.05 Output file: t-ext-sr-et.pdf 24AUG2023:15:01

Table 2.0301: Analysis of Splenic Response
Extended Treatment Phase (Week 24 Onward) and Overall MMB Period
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Week 96 in ET Phase					
Subjects ongoing and not reaching week 96 in ET phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 96 in ET Phase	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Splenic Response Rate at Week 96 in ET Phase					
Responder, n(%)	3 (7.0%)	3 (10.0%)	6 (8.2%)		
95% Exact CI	0.0146, 0.1906	0.0211, 0.2653	0.0308, 0.1704		
Non-Responder, n(%)	40 (93.0%)	27 (90.0%)	67 (91.8%)		
Baseline spleen volume not available	0	0	0		
Spleen volume at week 96 not available	35 (81.4%)	21 (70.0%)	56 (76.7%)		
>0% spleen volume increase at week 96	2 (4.7%)	2 (6.7%)	4 (5.5%)		
<35% spleen volume reduction from baseline	5 (11.6%)	6 (20.0%)	11 (15.1%)		
Discontinuation early at week 96	29 (67.4%)	20 (66.7%)	49 (67.1%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
For Switch (BAT->MMB) group, the baseline is the last assessment prior to or on the date of the 1st dose of MMB in the ET phase.
For Continuing (MMB->MMB) group, the baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 25JUN2019

Table 2.0301: Analysis of Splenic Response
Extended Treatment Phase (Week 24 Onward) and Overall MMB Period
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Week 108 in ET Phase					
Subjects ongoing and not reaching week 108 in ET phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 108 in ET Phase	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Splenic Response Rate at Week 108 in ET Phase					
Responder, n(%)	2 (4.7%)	3 (10.0%)	5 (6.8%)		
95% Exact CI	0.0057, 0.1581	0.0211, 0.2653	0.0226, 0.1526		
Non-Responder, n(%)	41 (95.3%)	27 (90.0%)	68 (93.2%)		
Baseline spleen volume not available	0	0	0		
Spleen volume at week 108 not available	36 (83.7%)	21 (70.0%)	57 (78.1%)		
>0% spleen volume increase at week 108	4 (9.3%)	2 (6.7%)	6 (8.2%)		
<35% spleen volume reduction from baseline	5 (11.6%)	6 (20.0%)	11 (15.1%)		
Discontinuation early at week 108	32 (74.4%)	21 (70.0%)	53 (72.6%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
For Switch (BAT->MMB) group, the baseline is the last assessment prior to or on the date of the 1st dose of MMB in the ET phase.
For Continuing (MMB->MMB) group, the baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

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Table 2.0301: Analysis of Splenic Response
Extended Treatment Phase (Week 24 Onward) and Overall MMB Period
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Week 120 in ET Phase					
Subjects ongoing and not reaching week 120 in ET phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 120 in ET Phase	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Splenic Response Rate at Week 120 in ET Phase					
Responder, n(%)	1 (2.3%)	2 (6.7%)	3 (4.1%)		
95% Exact CI	0.0006, 0.1229	0.0082, 0.2207	0.0086, 0.1154		
Non-Responder, n(%)	42 (97.7%)	28 (93.3%)	70 (95.9%)		
Baseline spleen volume not available	0	0	0		
Spleen volume at week 120 not available	38 (88.4%)	25 (83.3%)	63 (86.3%)		
>0% spleen volume increase at week 120	2 (4.7%)	1 (3.3%)	3 (4.1%)		
<35% spleen volume reduction from baseline	4 (9.3%)	3 (10.0%)	7 (9.6%)		
Discontinuation early at week 120	34 (79.1%)	23 (76.7%)	57 (78.1%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
For Switch (BAT->MMB) group, the baseline is the last assessment prior to or on the date of the 1st dose of MMB in the ET phase.
For Continuing (MMB->MMB) group, the baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 25JUN2019
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Table 2.0301: Analysis of Splenic Response
Extended Treatment Phase (Week 24 Onward) and Overall MMB Period
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Week 132 in ET Phase					
Subjects ongoing and not reaching week 132 in ET phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 132 in ET Phase	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Splenic Response Rate at Week 132 in ET Phase					
Responder, n(%)	0	2 (6.7%)	2 (2.7%)		
95% Exact CI	0.0000, 0.0822	0.0082, 0.2207	0.0033, 0.0955		
Non-Responder, n(%)	43 (100.0%)	28 (93.3%)	71 (97.3%)		
Baseline spleen volume not available	0	0	0		
Spleen volume at week 132 not available	40 (93.0%)	25 (83.3%)	65 (89.0%)		
>0% spleen volume increase at week 132	1 (2.3%)	2 (6.7%)	3 (4.1%)		
<35% spleen volume reduction from baseline	3 (7.0%)	3 (10.0%)	6 (8.2%)		
Discontinuation early at week 132	36 (83.7%)	24 (80.0%)	60 (82.2%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
For Switch (BAT->MMB) group, the baseline is the last assessment prior to or on the date of the 1st dose of MMB in the ET phase.
For Continuing (MMB->MMB) group, the baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

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Table 2.0301: Analysis of Splenic Response
Extended Treatment Phase (Week 24 Onward) and Overall MMB Period
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Week 144 in ET Phase					
Subjects ongoing and not reaching week 144 in ET phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 144 in ET Phase	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Splenic Response Rate at Week 144 in ET Phase					
Responder, n(%)	0	0	0		
95% Exact CI	0.0000, 0.0822	0.0000, 0.1157	0.0000, 0.0493		
Non-Responder, n(%)	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Baseline spleen volume not available	0	0	0		
Spleen volume at week 144 not available	41 (95.3%)	28 (93.3%)	69 (94.5%)		
>0% spleen volume increase at week 144	1 (2.3%)	1 (3.3%)	2 (2.7%)		
<35% spleen volume reduction from baseline	2 (4.7%)	2 (6.7%)	4 (5.5%)		
Discontinuation early at week 144	38 (88.4%)	27 (90.0%)	65 (89.0%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
For Switch (BAT->MMB) group, the baseline is the last assessment prior to or on the date of the 1st dose of MMB in the ET phase.
For Continuing (MMB->MMB) group, the baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

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Table 2.0301: Analysis of Splenic Response
Extended Treatment Phase (Week 24 Onward) and Overall MMB Period
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Week 156 in ET Phase					
Subjects ongoing and not reaching week 156 in ET phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 156 in ET Phase	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Splenic Response Rate at Week 156 in ET Phase					
Responder, n(%)	0	0	0		
95% Exact CI	0.0000, 0.0822	0.0000, 0.1157	0.0000, 0.0493		
Non-Responder, n(%)	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Baseline spleen volume not available	0	0	0		
Spleen volume at week 156 not available	43 (100.0%)	29 (96.7%)	72 (98.6%)		
>0% spleen volume increase at week 156	0	0	0		
<35% spleen volume reduction from baseline	0	1 (3.3%)	1 (1.4%)		
Discontinuation early at week 156	41 (95.3%)	28 (93.3%)	69 (94.5%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
For Switch (BAT->MMB) group, the baseline is the last assessment prior to or on the date of the 1st dose of MMB in the ET phase.
For Continuing (MMB->MMB) group, the baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 25JUN2019

Table 2.0401: Analysis of Splenic Response
Extended Treatment Phase (Week 24 Onward) and Overall MMB Period
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Spleen Volume (cm^3) at Baseline					
N	43	30	73	66	96
Mean (SD)	2333.5 (1300.53)	2069.6 (933.31)	2225.1 (1163.86)	2625.5 (1467.27)	2451.8 (1343.88)
Median	2357.6	2005.5	2049.3	2576.8	2317.2
Q1, Q3	1329.8, 3073.5	1289.3, 2723.4	1329.8, 2857.6	1340.9, 3541.6	1335.3, 3106.8
Min, Max	392, 6740	458, 4822	392, 6740	392, 6740	392, 6740
Splenic Response Rate at Any Timepoint of Overall Exposed to MMB Period					
Responder, n(%)				8 (12.1%)	13 (13.5%)
95% Exact CI				0.0538, 0.2249	0.0741, 0.2204
Splenic Response Rate at Any Timepoint of ET Phase					
Subjects Ongoing and not Reach the 1st Assessment Timepoint in ET Phase, n(%)	0	0	0		
Subjects Discontinued or Reached the 1st Assessment Timepoint in ET Phase, n(%)	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Responder, n(%)	7 (16.3%)	5 (16.7%)	12 (16.4%)		
95% Exact CI	0.0681, 0.3070	0.0564, 0.3472	0.0879, 0.2695		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 25JUN2019

Table 2.0401: Analysis of Splenic Response
Extended Treatment Phase (Week 24 Onward) and Overall MMB Period
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Week 24 in ET Phase					
Subjects ongoing and not reaching week 24 in ET phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 24 in ET Phase	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Splenic Response Rate at Week 24 in ET Phase					
Responder, n(%)	7 (16.3%)	2 (6.7%)	9 (12.3%)		
95% Exact CI	0.0681, 0.3070	0.0082, 0.2207	0.0580, 0.2212		
Non-Responder, n(%)	36 (83.7%)	28 (93.3%)	64 (87.7%)		
Baseline spleen volume not available	0	0	0		
Spleen volume at week 24 not available	13 (30.2%)	13 (43.3%)	26 (35.6%)		
>0% spleen volume increase at week 24	10 (23.3%)	6 (20.0%)	16 (21.9%)		
<35% spleen volume reduction from baseline	23 (53.5%)	15 (50.0%)	38 (52.1%)		
Discontinuation early at week 24	9 (20.9%)	12 (40.0%)	21 (28.8%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 25JUN2019

Table 2.0401: Analysis of Splenic Response
Extended Treatment Phase (Week 24 Onward) and Overall MMB Period
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Week 12 in ET Phase					
Subjects ongoing and not reaching week 12 in ET phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 12 in ET Phase	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Splenic Response Rate at Week 12 in ET Phase					
Responder, n(%)	5 (11.6%)	1 (3.3%)	6 (8.2%)		
95% Exact CI	0.0389, 0.2508	0.0008, 0.1722	0.0308, 0.1704		
Non-Responder, n(%)	38 (88.4%)	29 (96.7%)	67 (91.8%)		
Baseline spleen volume not available	0	0	0		
Spleen volume at week 12 not available	10 (23.3%)	11 (36.7%)	21 (28.8%)		
>0% spleen volume increase at week 12	13 (30.2%)	5 (16.7%)	18 (24.7%)		
<35% spleen volume reduction from baseline	28 (65.1%)	18 (60.0%)	46 (63.0%)		
Discontinuation early at week 12	1 (2.3%)	6 (20.0%)	7 (9.6%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 25JUN2019

Table 2.0401: Analysis of Splenic Response
Extended Treatment Phase (Week 24 Onward) and Overall MMB Period
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Week 36 in ET Phase					
Subjects ongoing and not reaching week 36 in ET phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 36 in ET Phase	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Splenic Response Rate at Week 36 in ET Phase					
Responder, n(%)	6 (14.0%)	3 (10.0%)	9 (12.3%)		
95% Exact CI	0.0530, 0.2793	0.0211, 0.2653	0.0580, 0.2212		
Non-Responder, n(%)	37 (86.0%)	27 (90.0%)	64 (87.7%)		
Baseline spleen volume not available	0	0	0		
Spleen volume at week 36 not available	19 (44.2%)	14 (46.7%)	33 (45.2%)		
>0% spleen volume increase at week 36	9 (20.9%)	5 (16.7%)	14 (19.2%)		
<35% spleen volume reduction from baseline	18 (41.9%)	13 (43.3%)	31 (42.5%)		
Discontinuation early at week 36	11 (25.6%)	14 (46.7%)	25 (34.2%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

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Table 2.0401: Analysis of Splenic Response
Extended Treatment Phase (Week 24 Onward) and Overall MMB Period
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Week 48 in ET Phase					
Subjects ongoing and not reaching week 48 in ET phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 48 in ET Phase	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Splenic Response Rate at Week 48 in ET Phase					
Responder, n(%)	4 (9.3%)	4 (13.3%)	8 (11.0%)		
95% Exact CI	0.0259, 0.2214	0.0376, 0.3072	0.0485, 0.2046		
Non-Responder, n(%)	39 (90.7%)	26 (86.7%)	65 (89.0%)		
Baseline spleen volume not available	0	0	0		
Spleen volume at week 48 not available	20 (46.5%)	15 (50.0%)	35 (47.9%)		
>0% spleen volume increase at week 48	8 (18.6%)	5 (16.7%)	13 (17.8%)		
<35% spleen volume reduction from baseline	19 (44.2%)	11 (36.7%)	30 (41.1%)		
Discontinuation early at week 48	18 (41.9%)	14 (46.7%)	32 (43.8%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

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Table 2.0401: Analysis of Splenic Response
Extended Treatment Phase (Week 24 Onward) and Overall MMB Period
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Week 60 in ET Phase					
Subjects ongoing and not reaching week 60 in ET phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 60 in ET Phase	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Splenic Response Rate at Week 60 in ET Phase					
Responder, n(%)	4 (9.3%)	4 (13.3%)	8 (11.0%)		
95% Exact CI	0.0259, 0.2214	0.0376, 0.3072	0.0485, 0.2046		
Non-Responder, n(%)	39 (90.7%)	26 (86.7%)	65 (89.0%)		
Baseline spleen volume not available	0	0	0		
Spleen volume at week 60 not available	24 (55.8%)	17 (56.7%)	41 (56.2%)		
>0% spleen volume increase at week 60	8 (18.6%)	4 (13.3%)	12 (16.4%)		
<35% spleen volume reduction from baseline	15 (34.9%)	9 (30.0%)	24 (32.9%)		
Discontinuation early at week 60	22 (51.2%)	15 (50.0%)	37 (50.7%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 25JUN2019

Table 2.0401: Analysis of Splenic Response
Extended Treatment Phase (Week 24 Onward) and Overall MMB Period
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Week 72 in ET Phase					
Subjects ongoing and not reaching week 72 in ET phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 72 in ET Phase	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Splenic Response Rate at Week 72 in ET Phase					
Responder, n(%)	3 (7.0%)	4 (13.3%)	7 (9.6%)		
95% Exact CI	0.0146, 0.1906	0.0376, 0.3072	0.0394, 0.1876		
Non-Responder, n(%)	40 (93.0%)	26 (86.7%)	66 (90.4%)		
Baseline spleen volume not available	0	0	0		
Spleen volume at week 72 not available	29 (67.4%)	19 (63.3%)	48 (65.8%)		
>0% spleen volume increase at week 72	6 (14.0%)	2 (6.7%)	8 (11.0%)		
<35% spleen volume reduction from baseline	11 (25.6%)	7 (23.3%)	18 (24.7%)		
Discontinuation early at week 72	25 (58.1%)	17 (56.7%)	42 (57.5%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Table 2.0401: Analysis of Splenic Response
Extended Treatment Phase (Week 24 Onward) and Overall MMB Period
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Week 84 in ET Phase					
Subjects ongoing and not reaching week 84 in ET phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 84 in ET Phase	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Splenic Response Rate at Week 84 in ET Phase					
Responder, n(%)	3 (7.0%)	3 (10.0%)	6 (8.2%)		
95% Exact CI	0.0146, 0.1906	0.0211, 0.2653	0.0308, 0.1704		
Non-Responder, n(%)	40 (93.0%)	27 (90.0%)	67 (91.8%)		
Baseline spleen volume not available	0	0	0		
Spleen volume at week 84 not available	30 (69.8%)	23 (76.7%)	53 (72.6%)		
>0% spleen volume increase at week 84	5 (11.6%)	1 (3.3%)	6 (8.2%)		
<35% spleen volume reduction from baseline	10 (23.3%)	4 (13.3%)	14 (19.2%)		
Discontinuation early at week 84	27 (62.8%)	19 (63.3%)	46 (63.0%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

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Table 2.0401: Analysis of Splenic Response
Extended Treatment Phase (Week 24 Onward) and Overall MMB Period
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Week 96 in ET Phase					
Subjects ongoing and not reaching week 96 in ET phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 96 in ET Phase	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Splenic Response Rate at Week 96 in ET Phase					
Responder, n(%)	3 (7.0%)	4 (13.3%)	7 (9.6%)		
95% Exact CI	0.0146, 0.1906	0.0376, 0.3072	0.0394, 0.1876		
Non-Responder, n(%)	40 (93.0%)	26 (86.7%)	66 (90.4%)		
Baseline spleen volume not available	0	0	0		
Spleen volume at week 96 not available	35 (81.4%)	21 (70.0%)	56 (76.7%)		
>0% spleen volume increase at week 96	2 (4.7%)	1 (3.3%)	3 (4.1%)		
<35% spleen volume reduction from baseline	5 (11.6%)	5 (16.7%)	10 (13.7%)		
Discontinuation early at week 96	29 (67.4%)	20 (66.7%)	49 (67.1%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 25JUN2019

Table 2.0401: Analysis of Splenic Response
Extended Treatment Phase (Week 24 Onward) and Overall MMB Period
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Week 108 in ET Phase					
Subjects ongoing and not reaching week 108 in ET phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 108 in ET Phase	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Splenic Response Rate at Week 108 in ET Phase					
Responder, n(%)	2 (4.7%)	3 (10.0%)	5 (6.8%)		
95% Exact CI	0.0057, 0.1581	0.0211, 0.2653	0.0226, 0.1526		
Non-Responder, n(%)	41 (95.3%)	27 (90.0%)	68 (93.2%)		
Baseline spleen volume not available	0	0	0		
Spleen volume at week 108 not available	36 (83.7%)	21 (70.0%)	57 (78.1%)		
>0% spleen volume increase at week 108	4 (9.3%)	1 (3.3%)	5 (6.8%)		
<35% spleen volume reduction from baseline	5 (11.6%)	6 (20.0%)	11 (15.1%)		
Discontinuation early at week 108	32 (74.4%)	21 (70.0%)	53 (72.6%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Table 2.0401: Analysis of Splenic Response
Extended Treatment Phase (Week 24 Onward) and Overall MMB Period
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Week 120 in ET Phase					
Subjects ongoing and not reaching week 120 in ET phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 120 in ET Phase	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Splenic Response Rate at Week 120 in ET Phase					
Responder, n(%)	1 (2.3%)	2 (6.7%)	3 (4.1%)		
95% Exact CI	0.0006, 0.1229	0.0082, 0.2207	0.0086, 0.1154		
Non-Responder, n(%)	42 (97.7%)	28 (93.3%)	70 (95.9%)		
Baseline spleen volume not available	0	0	0		
Spleen volume at week 120 not available	38 (88.4%)	25 (83.3%)	63 (86.3%)		
>0% spleen volume increase at week 120	2 (4.7%)	1 (3.3%)	3 (4.1%)		
<35% spleen volume reduction from baseline	4 (9.3%)	3 (10.0%)	7 (9.6%)		
Discontinuation early at week 120	34 (79.1%)	23 (76.7%)	57 (78.1%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 25JUN2019

Table 2.0401: Analysis of Splenic Response
Extended Treatment Phase (Week 24 Onward) and Overall MMB Period
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Week 132 in ET Phase					
Subjects ongoing and not reaching week 132 in ET phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 132 in ET Phase	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Splenic Response Rate at Week 132 in ET Phase					
Responder, n(%)	0	2 (6.7%)	2 (2.7%)		
95% Exact CI	0.0000, 0.0822	0.0082, 0.2207	0.0033, 0.0955		
Non-Responder, n(%)	43 (100.0%)	28 (93.3%)	71 (97.3%)		
Baseline spleen volume not available	0	0	0		
Spleen volume at week 132 not available	40 (93.0%)	25 (83.3%)	65 (89.0%)		
>0% spleen volume increase at week 132	1 (2.3%)	1 (3.3%)	2 (2.7%)		
<35% spleen volume reduction from baseline	3 (7.0%)	3 (10.0%)	6 (8.2%)		
Discontinuation early at week 132	36 (83.7%)	24 (80.0%)	60 (82.2%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 25JUN2019

Table 2.0401: Analysis of Splenic Response
Extended Treatment Phase (Week 24 Onward) and Overall MMB Period
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Week 144 in ET Phase					
Subjects ongoing and not reaching week 144 in ET phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 144 in ET Phase	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Splenic Response Rate at Week 144 in ET Phase					
Responder, n(%)	0	0	0		
95% Exact CI	0.0000, 0.0822	0.0000, 0.1157	0.0000, 0.0493		
Non-Responder, n(%)	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Baseline spleen volume not available	0	0	0		
Spleen volume at week 144 not available	41 (95.3%)	28 (93.3%)	69 (94.5%)		
>0% spleen volume increase at week 144	1 (2.3%)	1 (3.3%)	2 (2.7%)		
<35% spleen volume reduction from baseline	2 (4.7%)	2 (6.7%)	4 (5.5%)		
Discontinuation early at week 144	38 (88.4%)	27 (90.0%)	65 (89.0%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

Data Extracted: CRF data: 25JUN2019

Table 2.0401: Analysis of Splenic Response
Extended Treatment Phase (Week 24 Onward) and Overall MMB Period
ITT-Anemic Analysis Set

	Extended Treatment Phase			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)	MMB in RT (N=66)	Total (N=96)
Week 156 in ET Phase					
Subjects ongoing and not reaching week 156 in ET phase	0	0	0		
Subjects Evaluable for Splenic Response Rate at Week 156 in ET Phase	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Splenic Response Rate at Week 156 in ET Phase					
Responder, n(%)	0	0	0		
95% Exact CI	0.0000, 0.0822	0.0000, 0.1157	0.0000, 0.0493		
Non-Responder, n(%)	43 (100.0%)	30 (100.0%)	73 (100.0%)		
Baseline spleen volume not available	0	0	0		
Spleen volume at week 156 not available	43 (100.0%)	29 (96.7%)	72 (98.6%)		
>0% spleen volume increase at week 156	0	0	0		
<35% spleen volume reduction from baseline	0	1 (3.3%)	1 (1.4%)		
Discontinuation early at week 156	41 (95.3%)	28 (93.3%)	69 (94.5%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Baseline is the last assessment prior to or on the date of randomization.
Number of subjects evaluable for analysis at a visit = Number of subjects in the analysis set - number of subjects ongoing and not reach the visit.
Denominator of response rate calculation is the number of subjects evaluable for analysis at a visit.

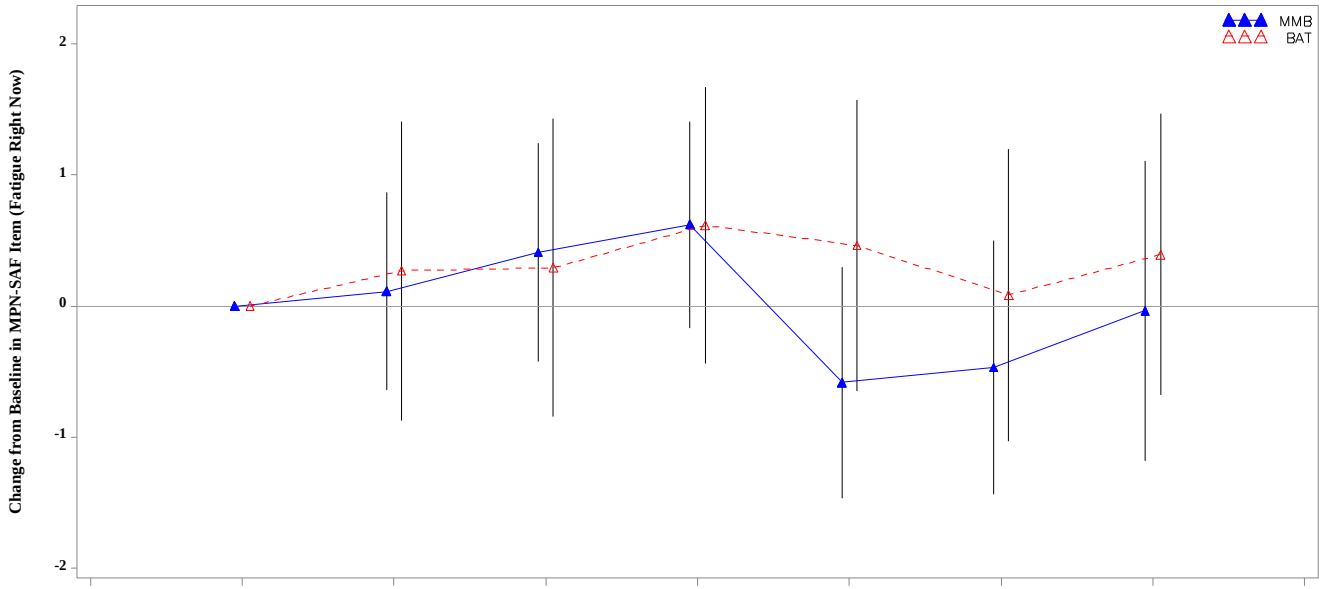
Data Extracted: CRF data: 25JUN2019

2.4 Symptomansprechen

2.4.1 MPN-SAF

GSK Oncology
Study GS-US-352-1214

Figure 2.3301: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Individual MPN-SAF Items Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set
Parameter=BFI01-Fatigue Right Now



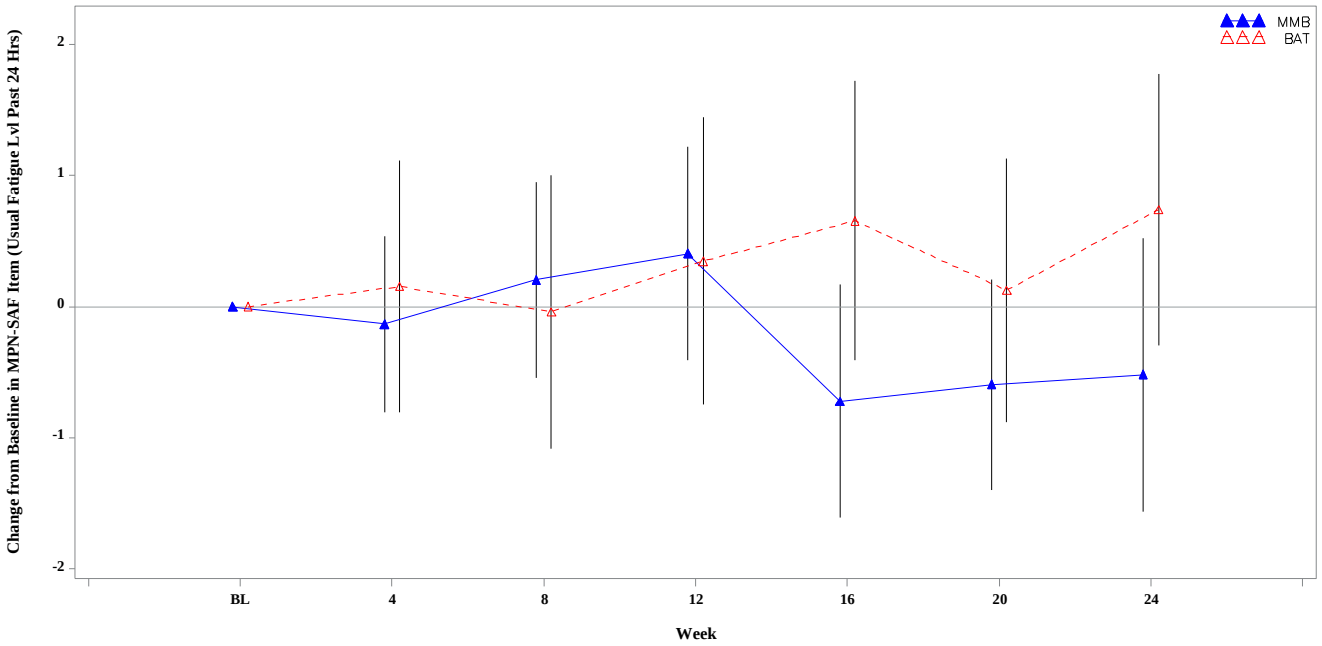
MMB	(n)	50	45	44	37	36	32	27
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF= Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-rt.pdf 24AUG2023:16:51

Figure 2.3301: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Individual MPN-SAF Items Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=BFI01-Usual Fatigue Lvl Past 24 Hrs



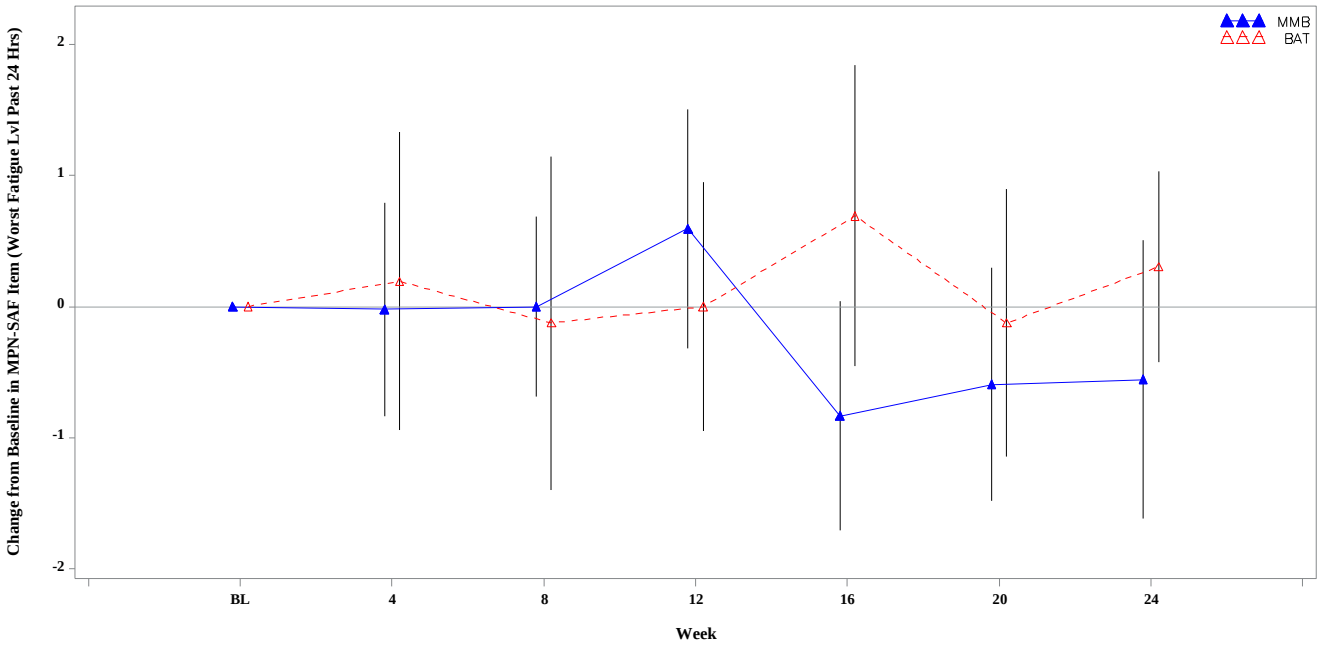
MMB	(n)	50	45	44	37	36	32	27
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF= Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-rt.pdf 24AUG2023:16:51

Figure 2.3301: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Individual MPN-SAF Items Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=BFI01-Worst Fatigue Lvl Past 24 Hrs



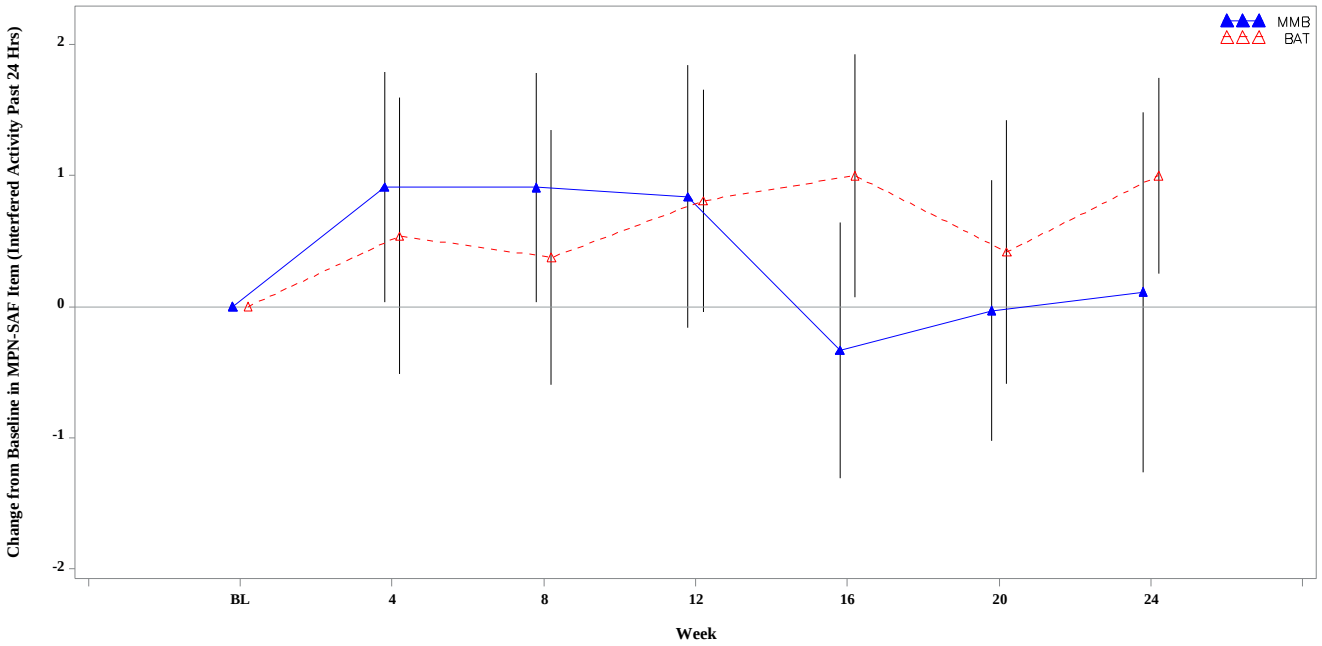
MMB	(n)	50	45	44	37	36	32	27
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF= Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-rt.pdf 24AUG2023:16:51

Figure 2.3301: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Individual MPN-SAF Items Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=BFI01-Interfered Activity Past 24 Hrs



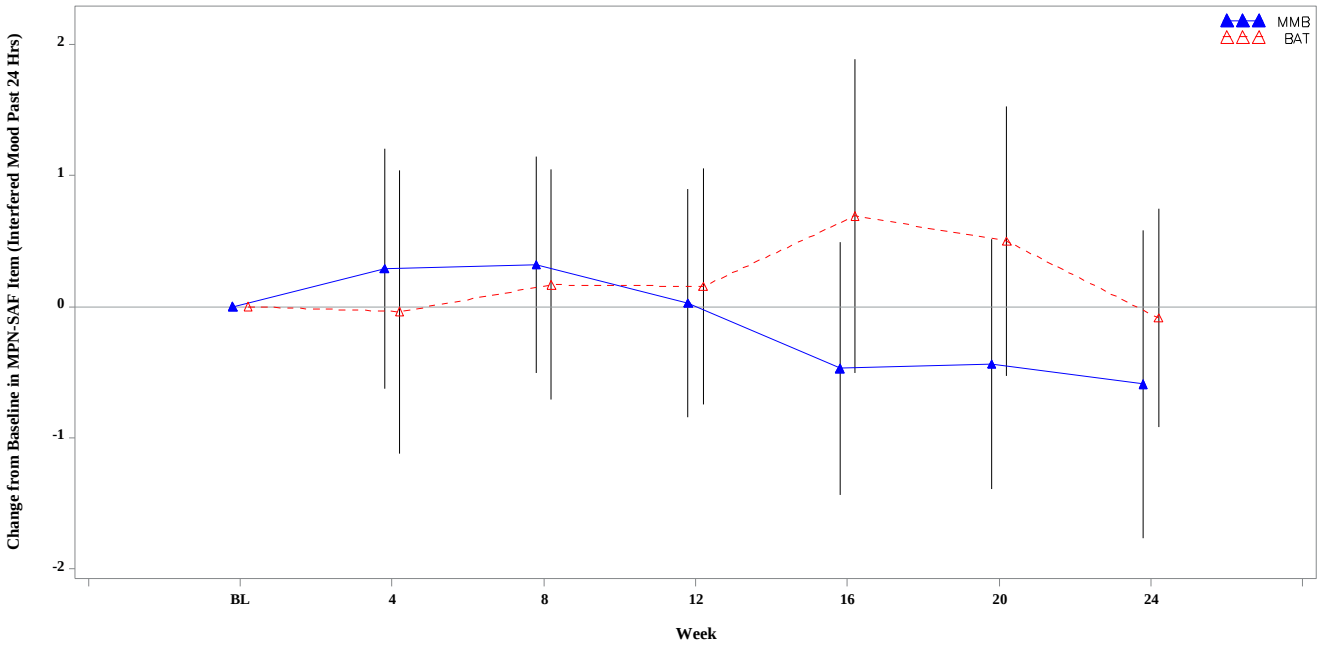
MMB	(n)	50	45	44	37	36	32	27
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF= Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-rt.pdf 24AUG2023:16:51

Figure 2.3301: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Individual MPN-SAF Items Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=BFI01-Interfered Mood Past 24 Hrs



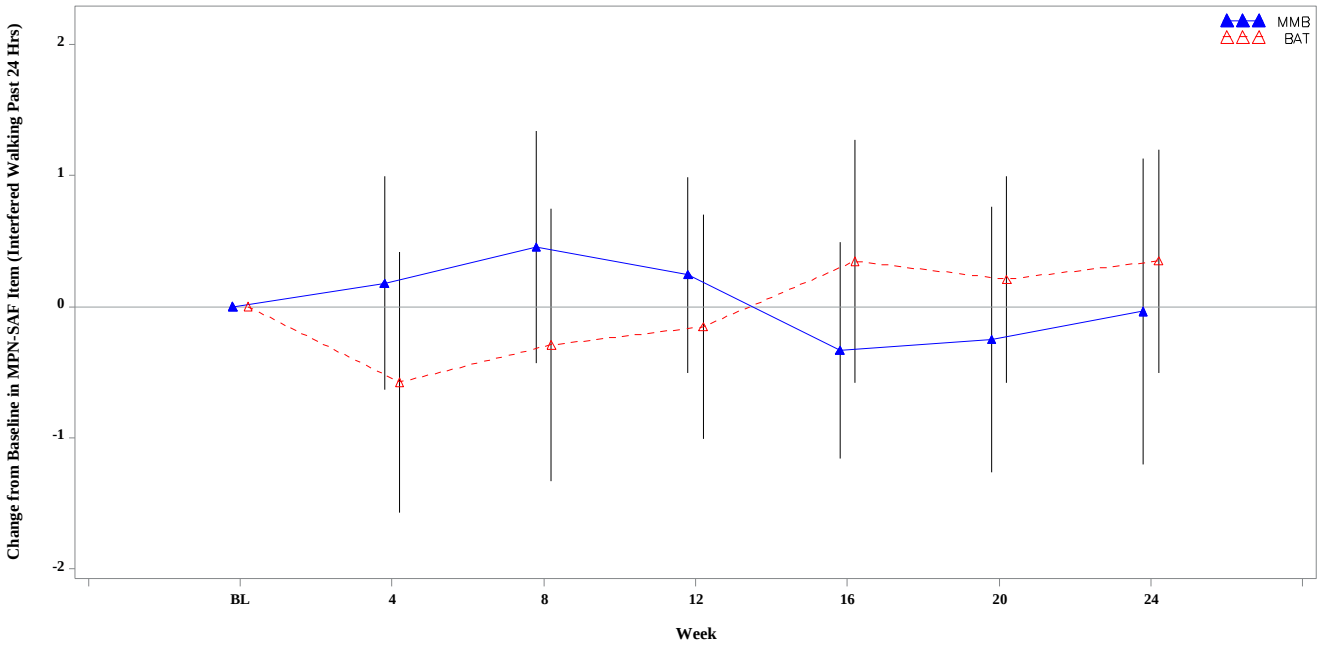
MMB	(n)	50	45	44	37	36	32	27
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF= Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-rt.pdf 24AUG2023:16:51

Figure 2.3301: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Individual MPN-SAF Items Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=BFI01-Interfered Walking Past 24 Hrs



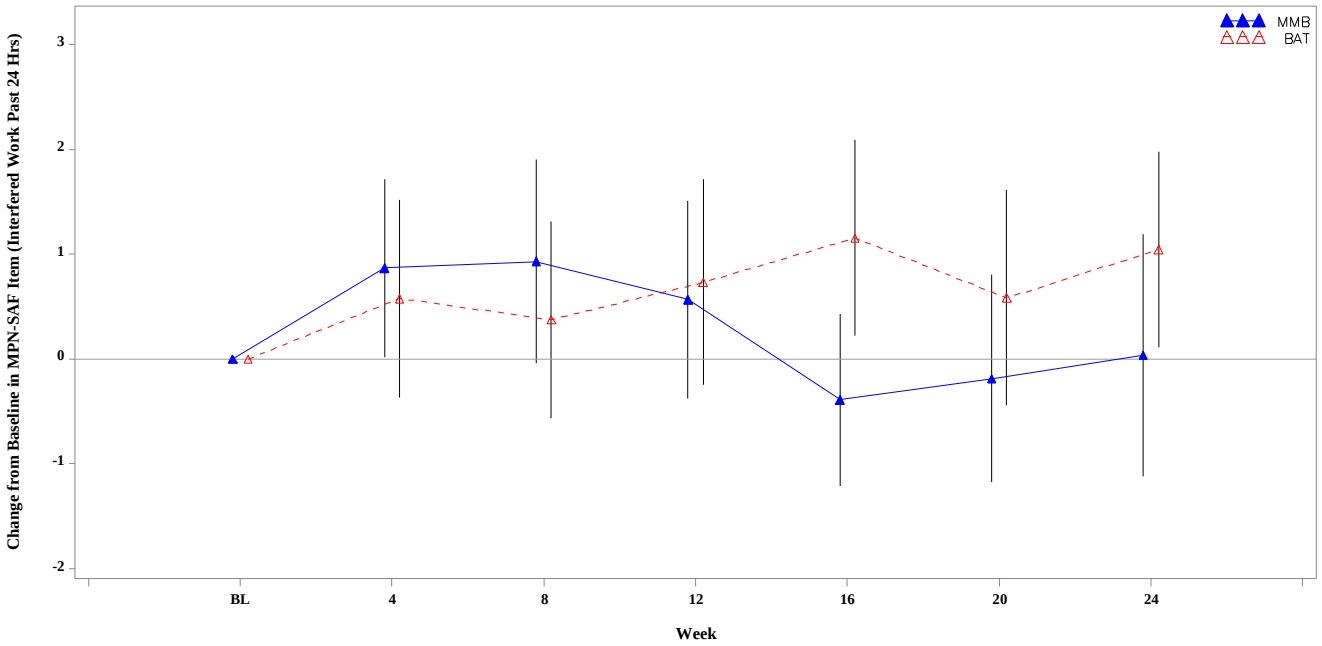
MMB	(n)	50	45	44	37	36	32	27
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF= Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-rt.pdf 24AUG2023:16:51

Figure 2.3301: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Individual MPN-SAF Items Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=BFI01-Interfered Work Past 24 Hrs



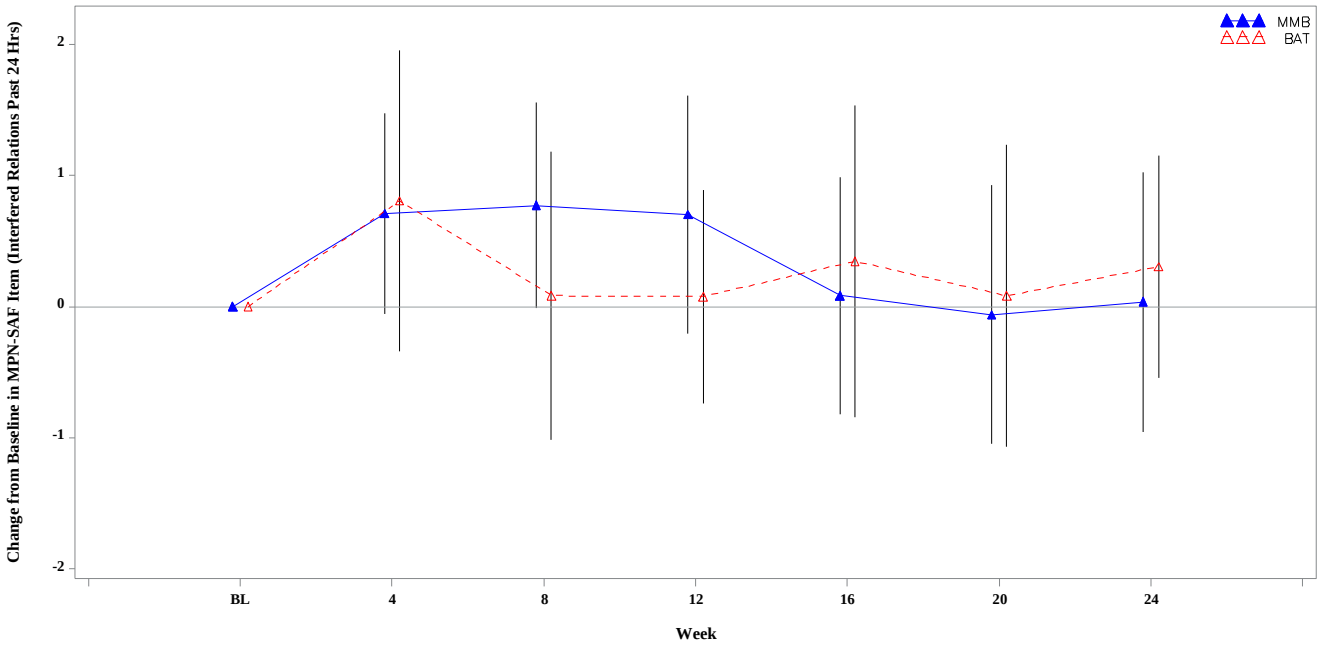
MMB	(n)	50	45	44	37	36	32	27
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF= Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-rt.pdf 24AUG2023:16:51

Figure 2.3301: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Individual MPN-SAF Items Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=BFI01-Interfered Relations Past 24 Hrs



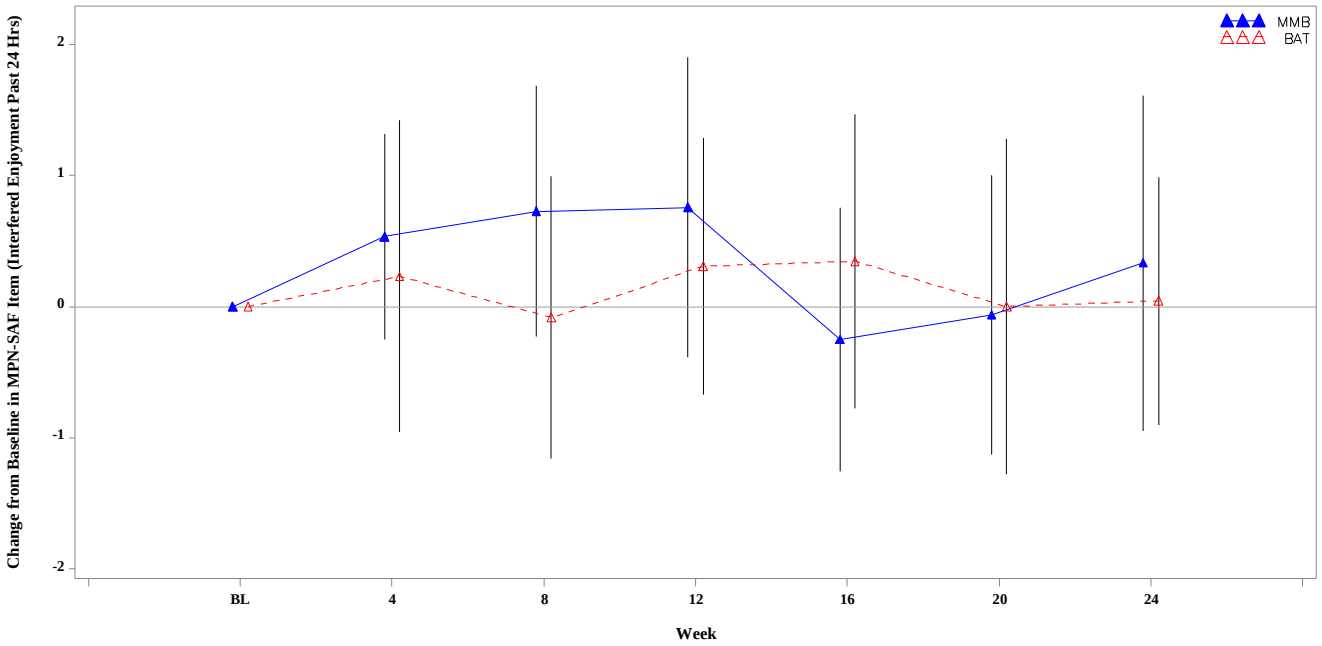
MMB	(n)	50	45	44	37	36	32	27
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF= Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-rt.pdf 24AUG2023:16:51

Figure 2.3301: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Individual MPN-SAF Items Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=BFI01-Interfered Enjoyment Past 24 Hrs



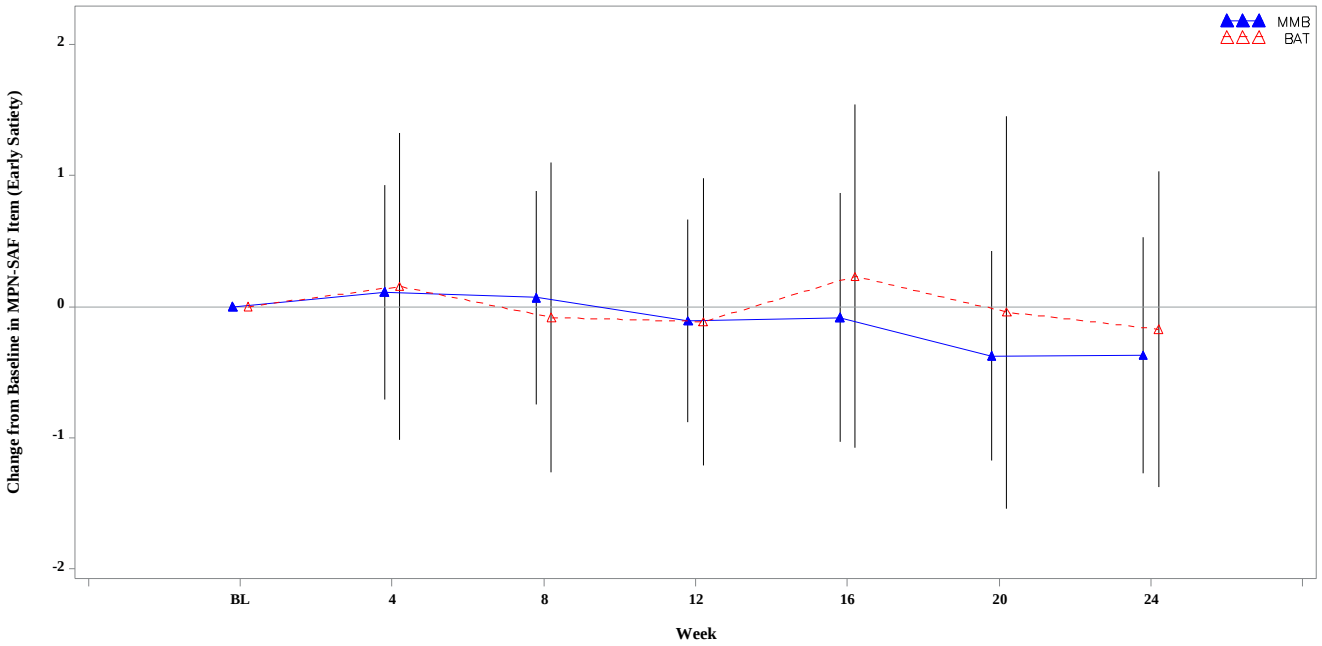
MMB	(n)	50	45	44	37	36	32	27
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF= Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-rt.pdf 24AUG2023:16:51

Figure 2.3301: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Individual MPN-SAF Items Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Early Satiety



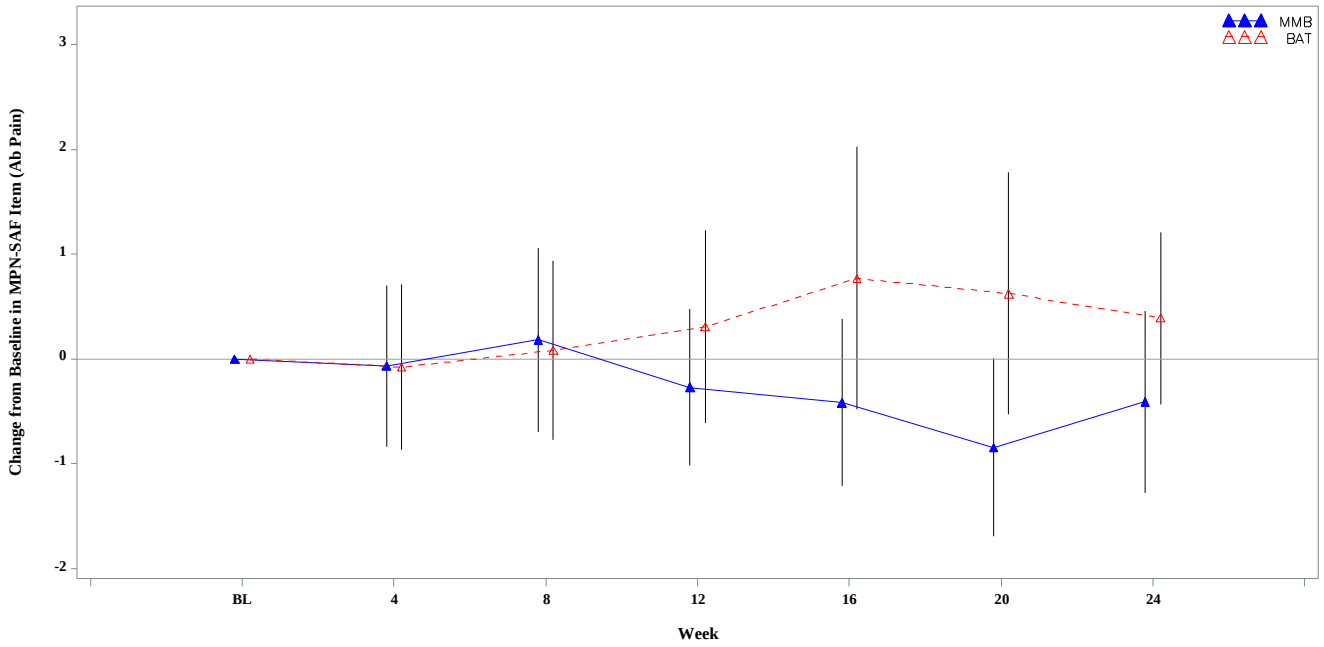
MMB	(n)	50	45	44	37	36	32	27
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF= Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-rt.pdf 24AUG2023:16:51

Figure 2.3301: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Individual MPN-SAF Items Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Ab Pain



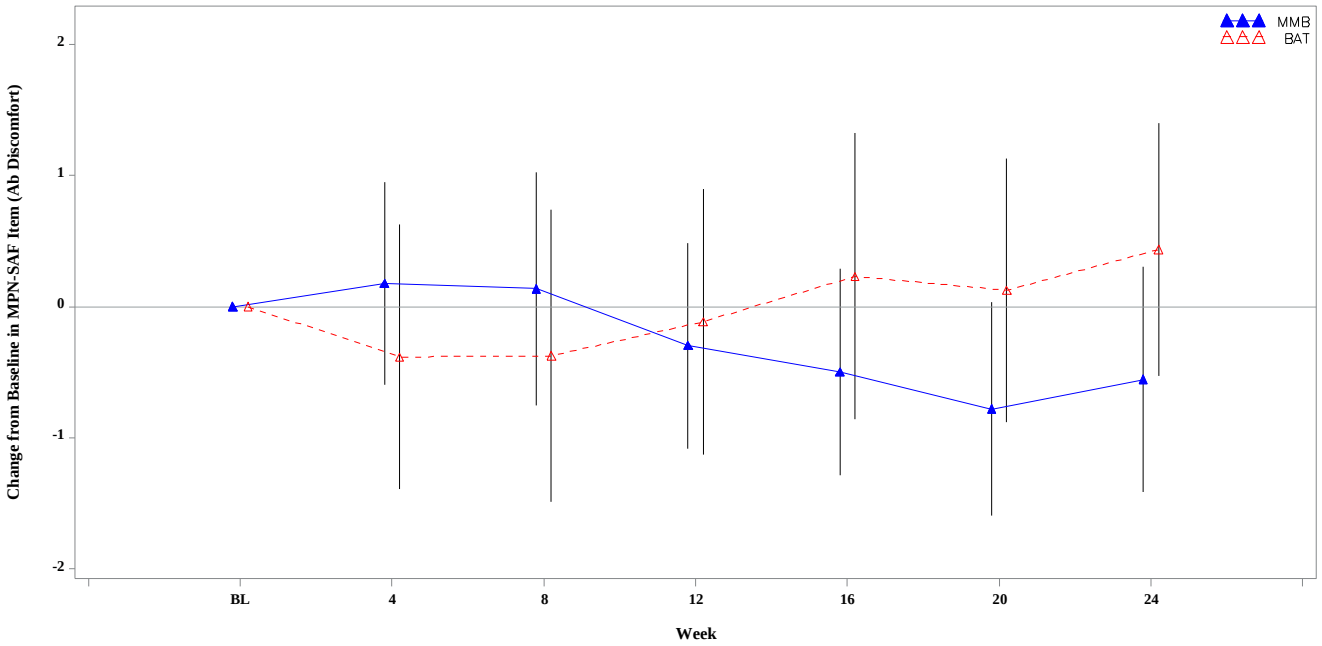
MMB	(n)	50	45	44	37	36	32	27
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF= Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-rt.pdf 24AUG2023:16:51

Figure 2.3301: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Individual MPN-SAF Items Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Ab Discomfort



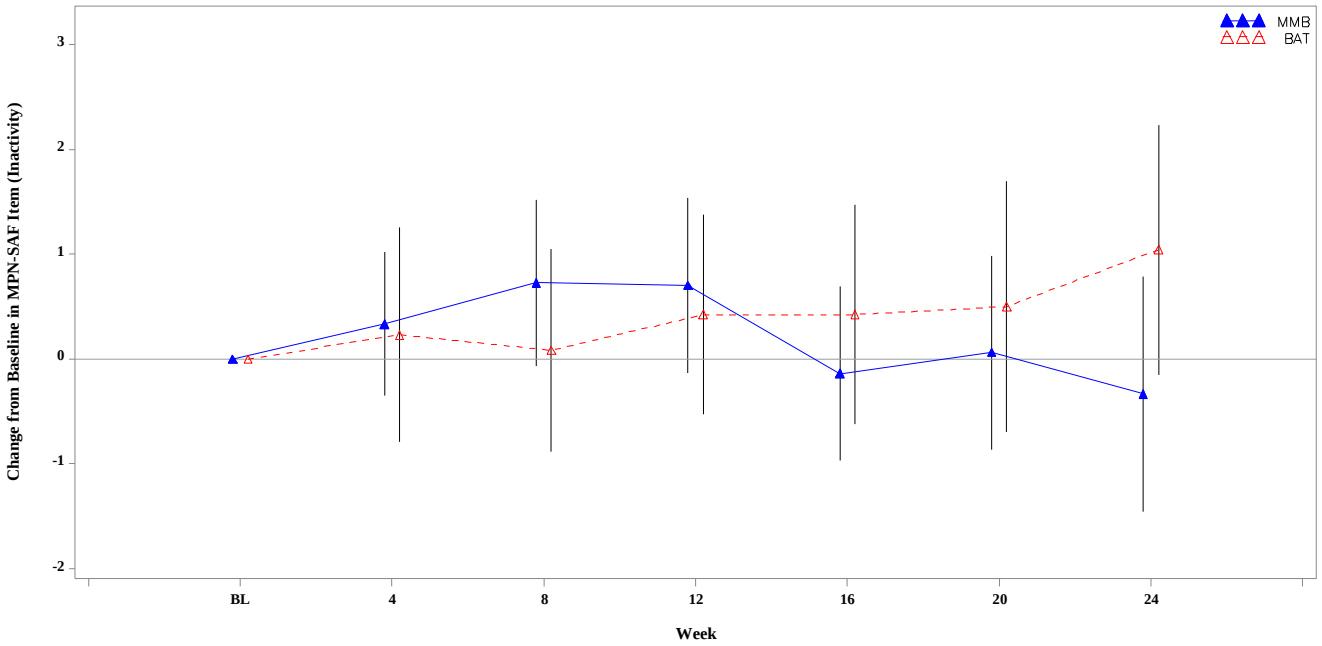
MMB	(n)	50	45	44	37	36	32	27
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF= Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-rt.pdf 24AUG2023:16:51

Figure 2.3301: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Individual MPN-SAF Items Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Inactivity



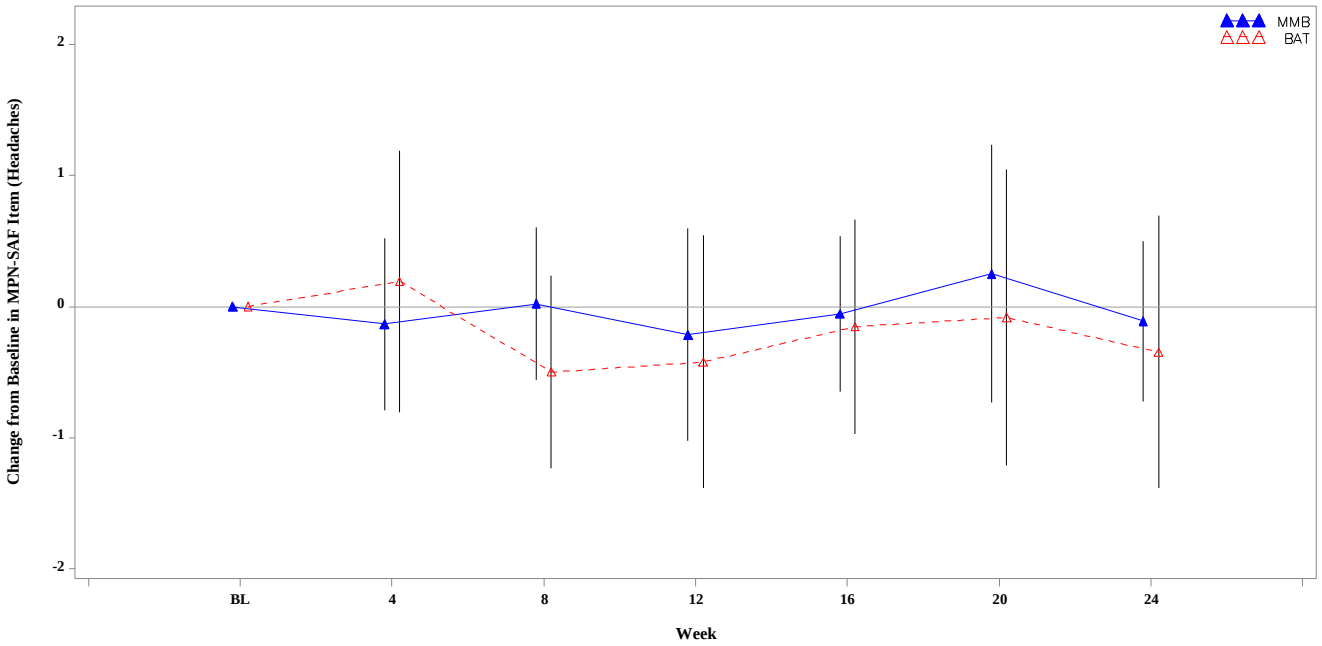
MMB	(n)	50	45	44	37	36	32	27
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF= Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-rt.pdf 24AUG2023:16:51

Figure 2.3301: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Individual MPN-SAF Items Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Headaches



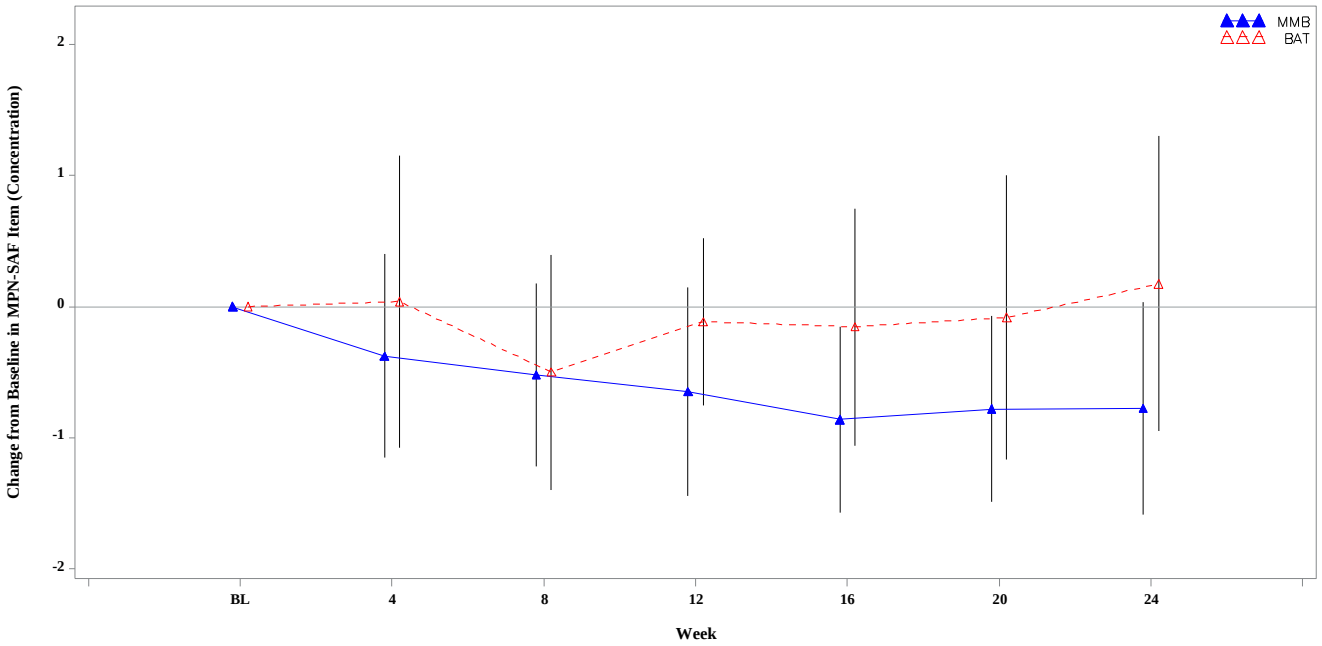
MMB	(n)	50	45	44	37	36	32	27
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF= Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-rt.pdf 24AUG2023:16:51

Figure 2.3301: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Individual MPN-SAF Items Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Concentration



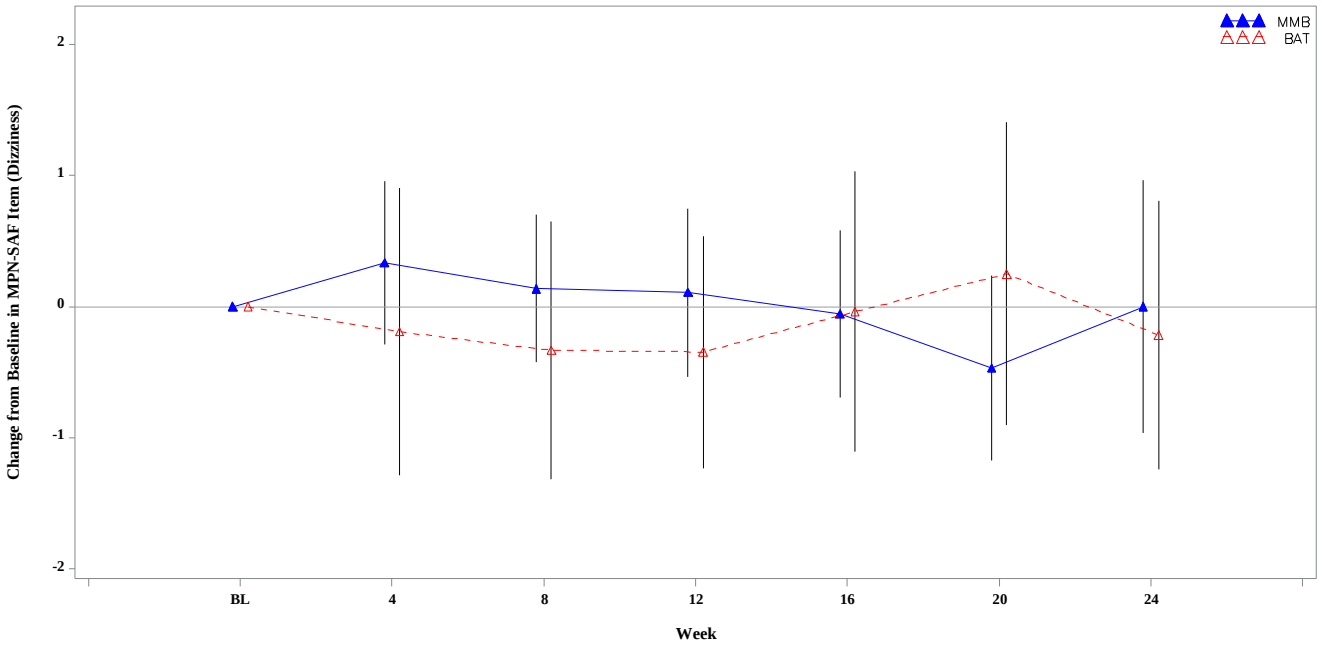
MMB	(n)	50	45	44	37	36	32	27
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF= Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-rt.pdf 24AUG2023:16:51

Figure 2.3301: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Individual MPN-SAF Items Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Dizziness



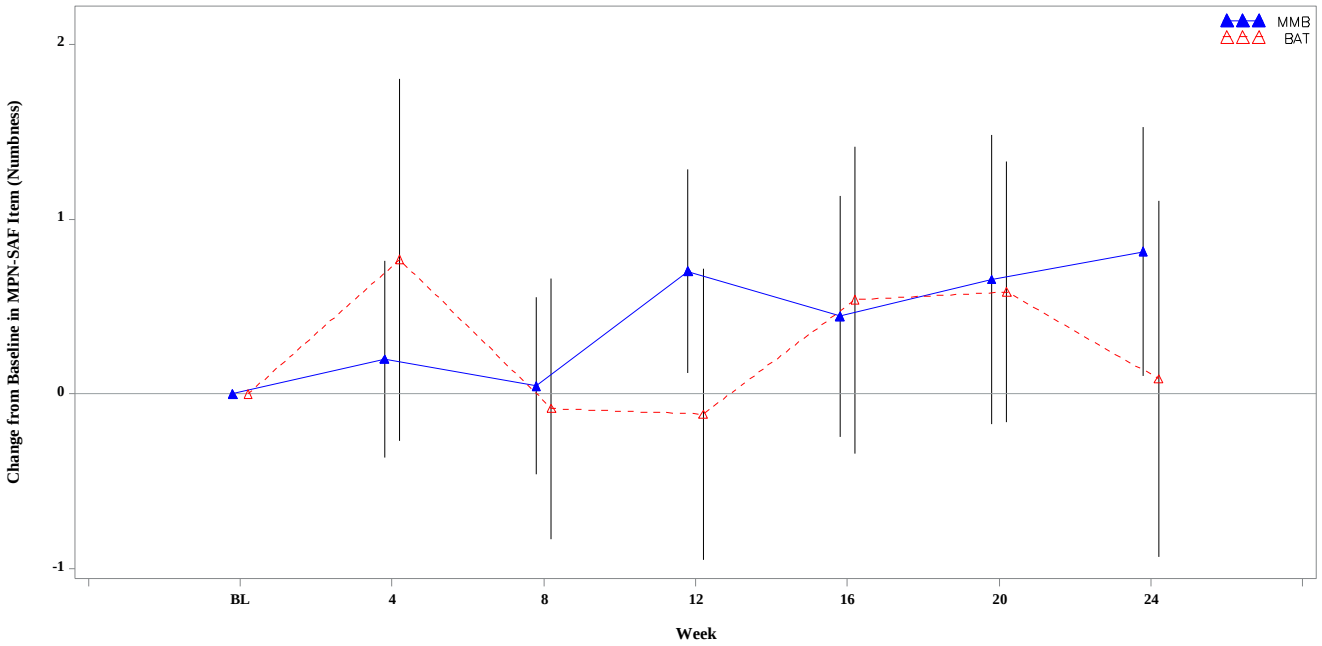
MMB	(n)	50	45	44	37	36	32	27
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF= Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-rt.pdf 24AUG2023:16:51

Figure 2.3301: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Individual MPN-SAF Items Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Numbness



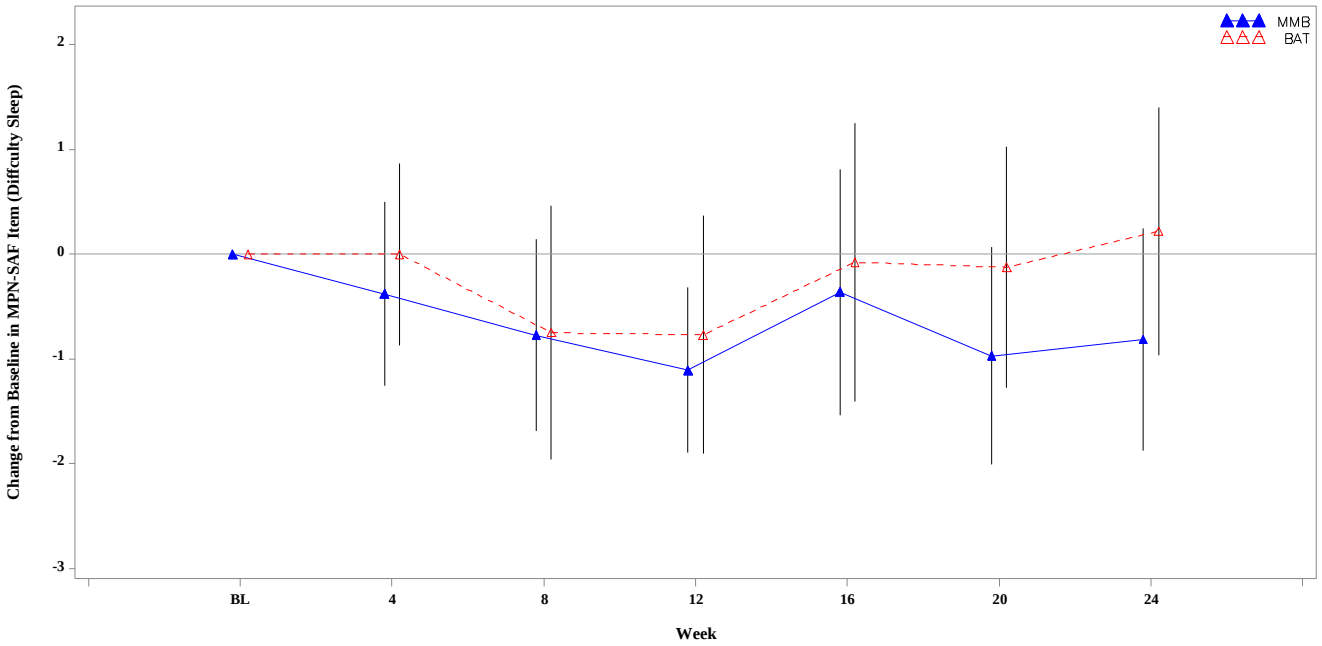
MMB	(n)	50	45	44	37	36	32	27
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF= Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-rt.pdf 24AUG2023:16:51

Figure 2.3301: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Individual MPN-SAF Items Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Diffculty Sleep



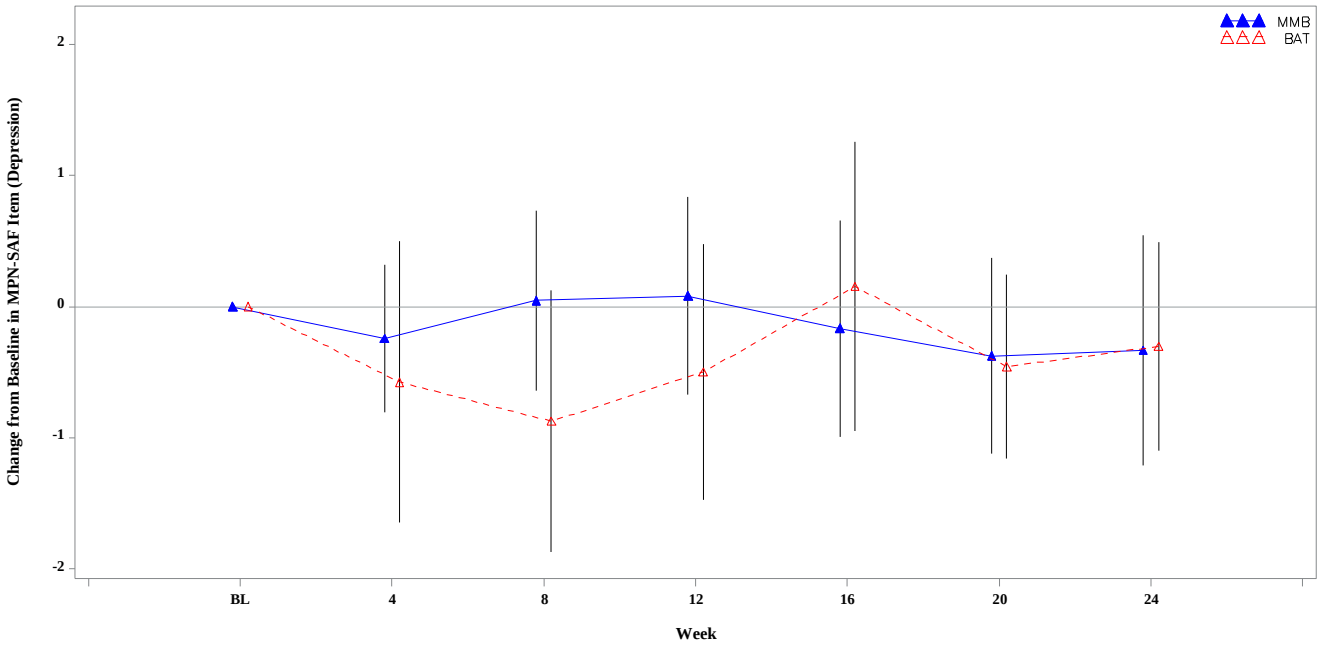
MMB	(n)	50	45	44	37	36	32	27
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF= Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-rt.pdf 24AUG2023:16:51

Figure 2.3301: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Individual MPN-SAF Items Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Depression



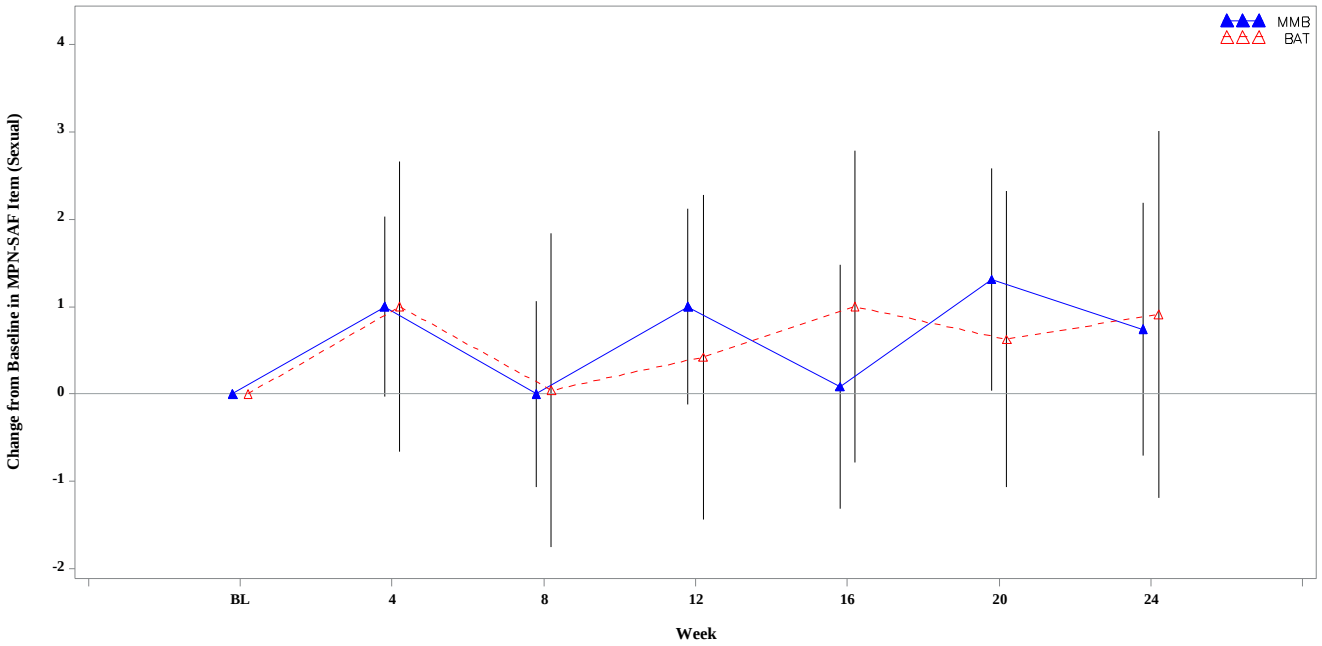
MMB	(n)	50	45	44	37	36	32	27
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF= Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-rt.pdf 24AUG2023:16:51

Figure 2.3301: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Individual MPN-SAF Items Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Sexual



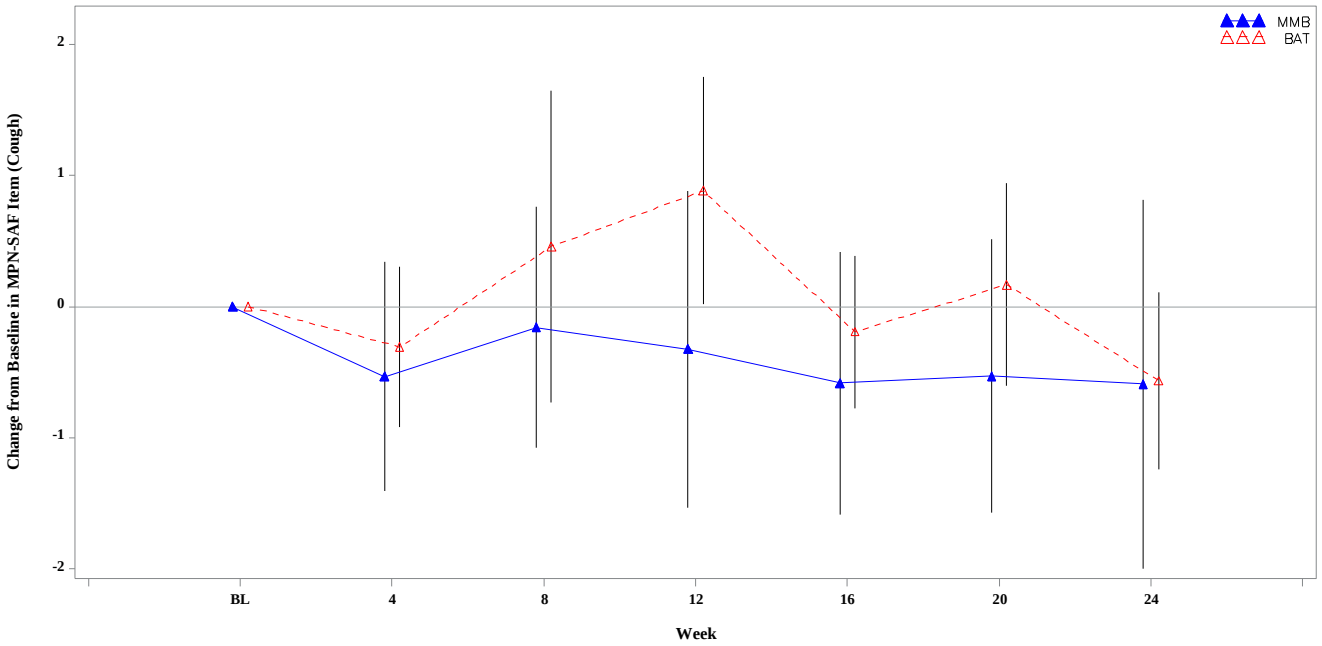
MMB	(n)	50	45	44	37	36	32	27
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF= Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-rt.pdf 24AUG2023:16:51

Figure 2.3301: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Individual MPN-SAF Items Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Cough



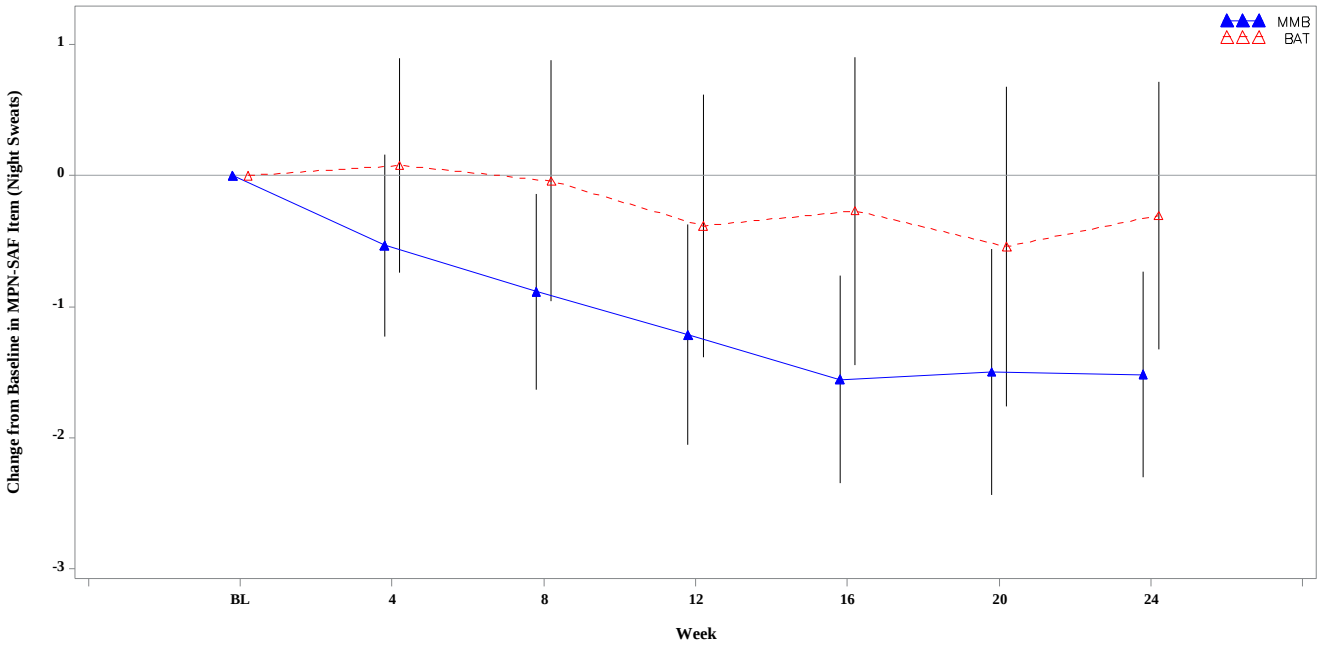
MMB	(n)	50	45	44	37	36	32	27
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF= Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-rt.pdf 24AUG2023:16:51

Figure 2.3301: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Individual MPN-SAF Items Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Night Sweats



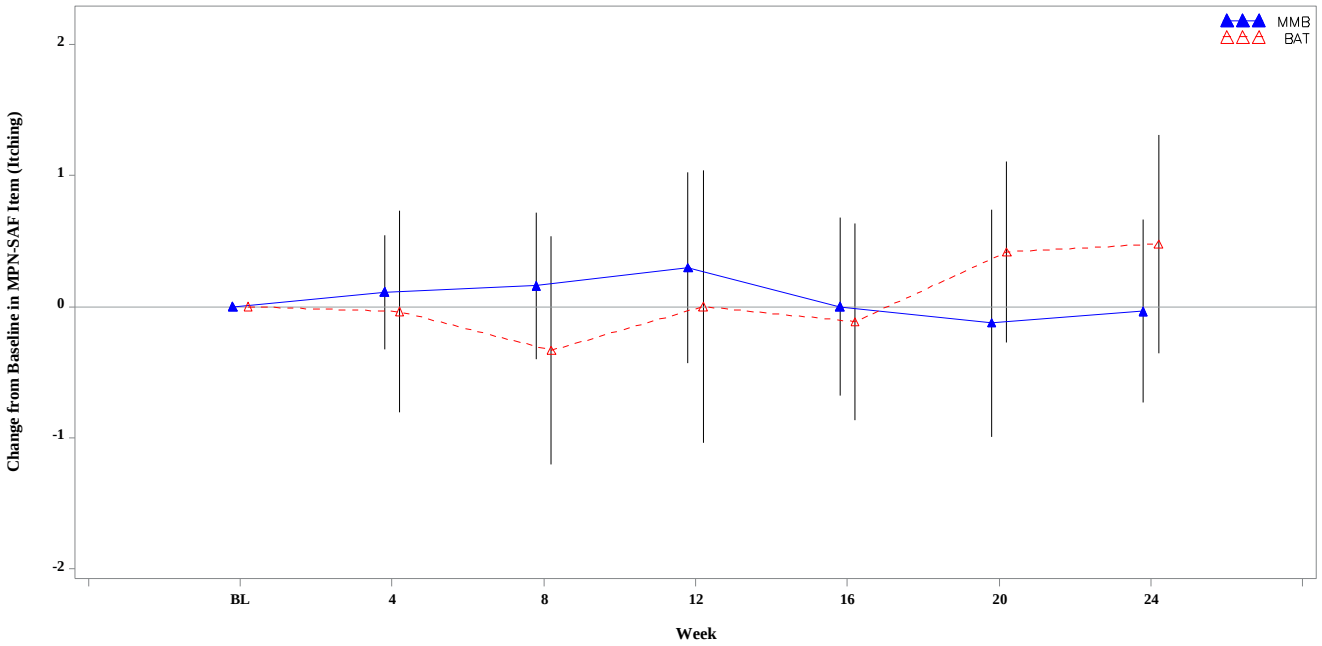
MMB	(n)	50	45	44	37	36	32	27
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF= Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-rt.pdf 24AUG2023:16:51

Figure 2.3301: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Individual MPN-SAF Items Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Itching



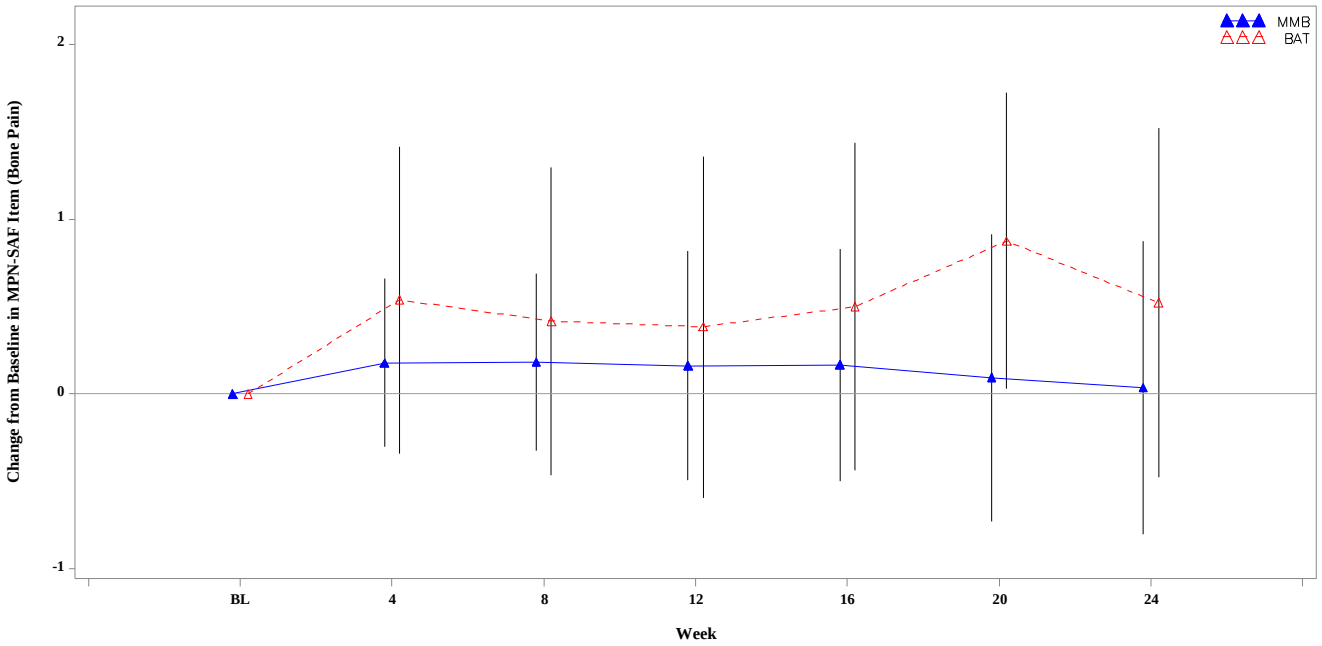
MMB	(n)	50	45	44	37	36	32	27
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF= Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-rt.pdf 24AUG2023:16:51

Figure 2.3301: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Individual MPN-SAF Items Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Bone Pain



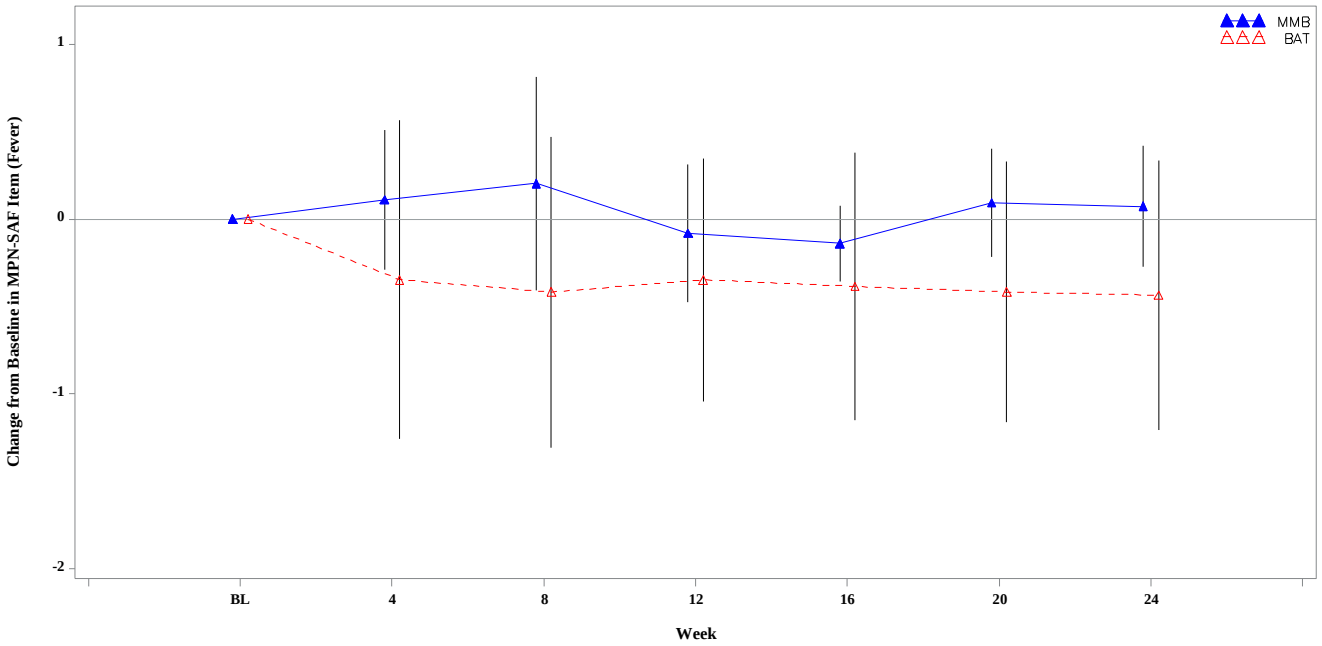
MMB	(n)	50	45	44	37	36	32	27
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF= Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-rt.pdf 24AUG2023:16:52

Figure 2.3301: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Individual MPN-SAF Items Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Fever



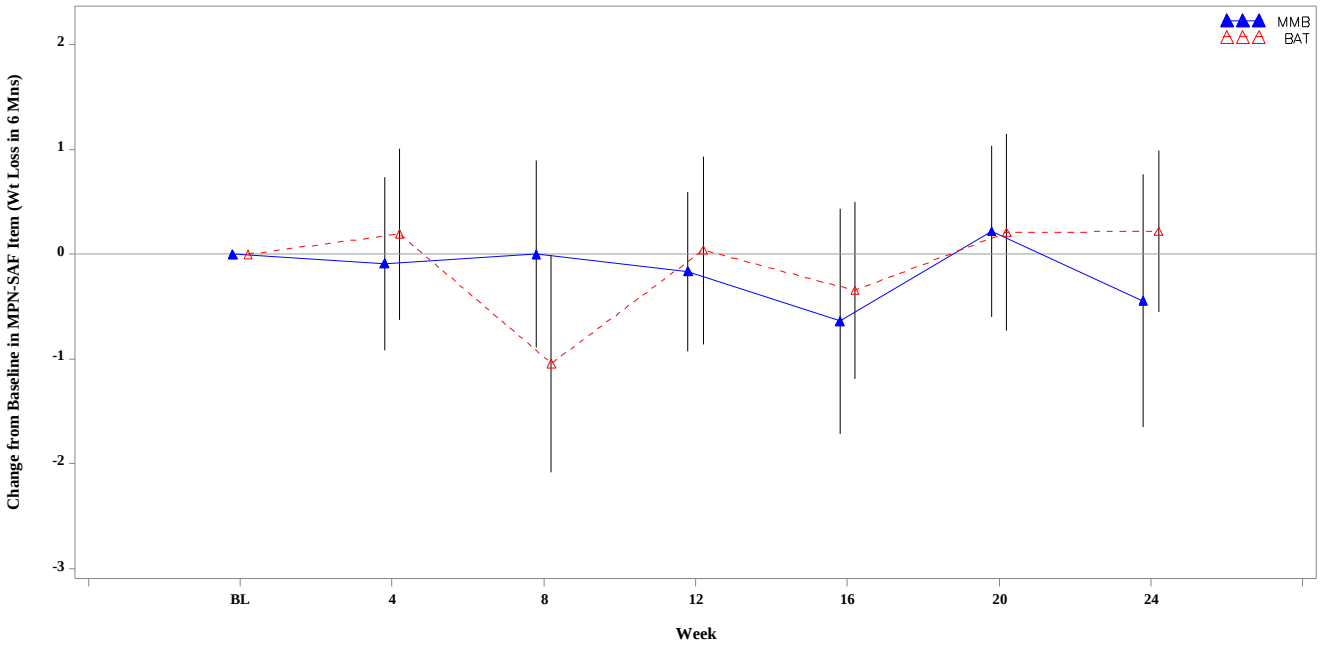
MMB	(n)	50	45	44	37	36	32	27
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF= Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-rt.pdf 24AUG2023:16:52

Figure 2.3301: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Individual MPN-SAF Items Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Diffculty Pst Wk: Wt Loss in 6 Mns



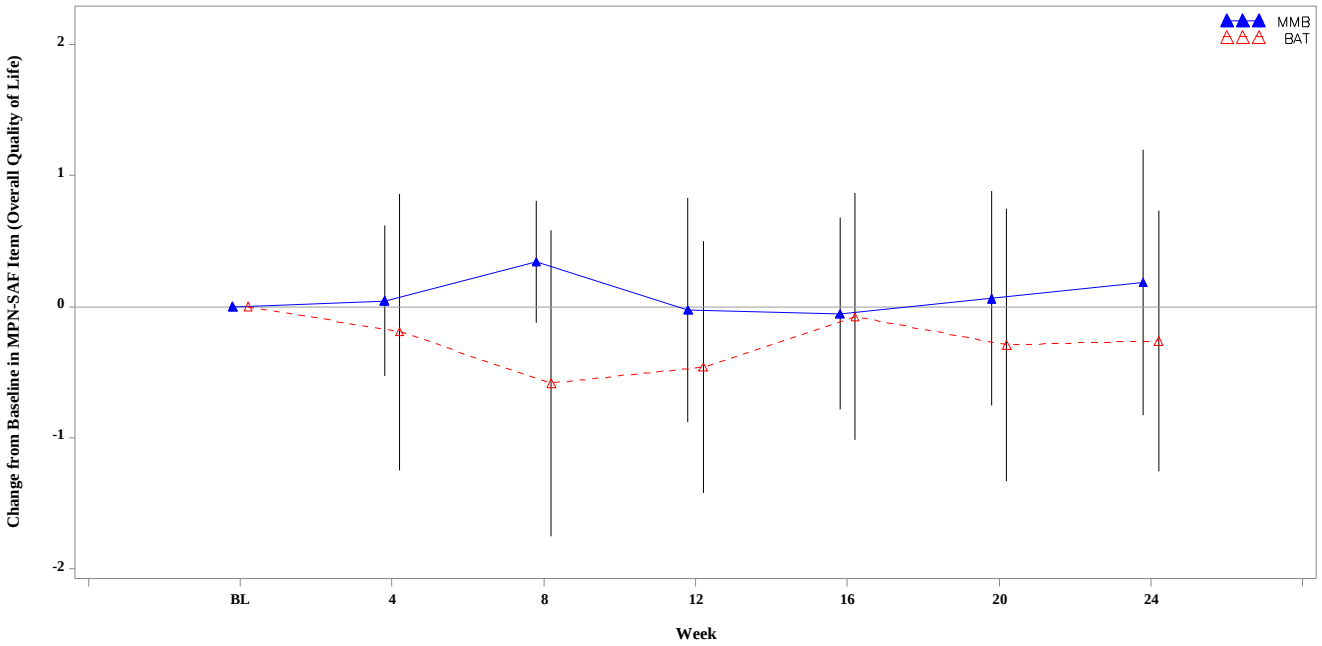
MMB	(n)	50	45	44	37	36	32	27
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF= Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-rt.pdf 24AUG2023:16:52

Figure 2.3301: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Individual MPN-SAF Items Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=MPN01-Overall Quality of Life

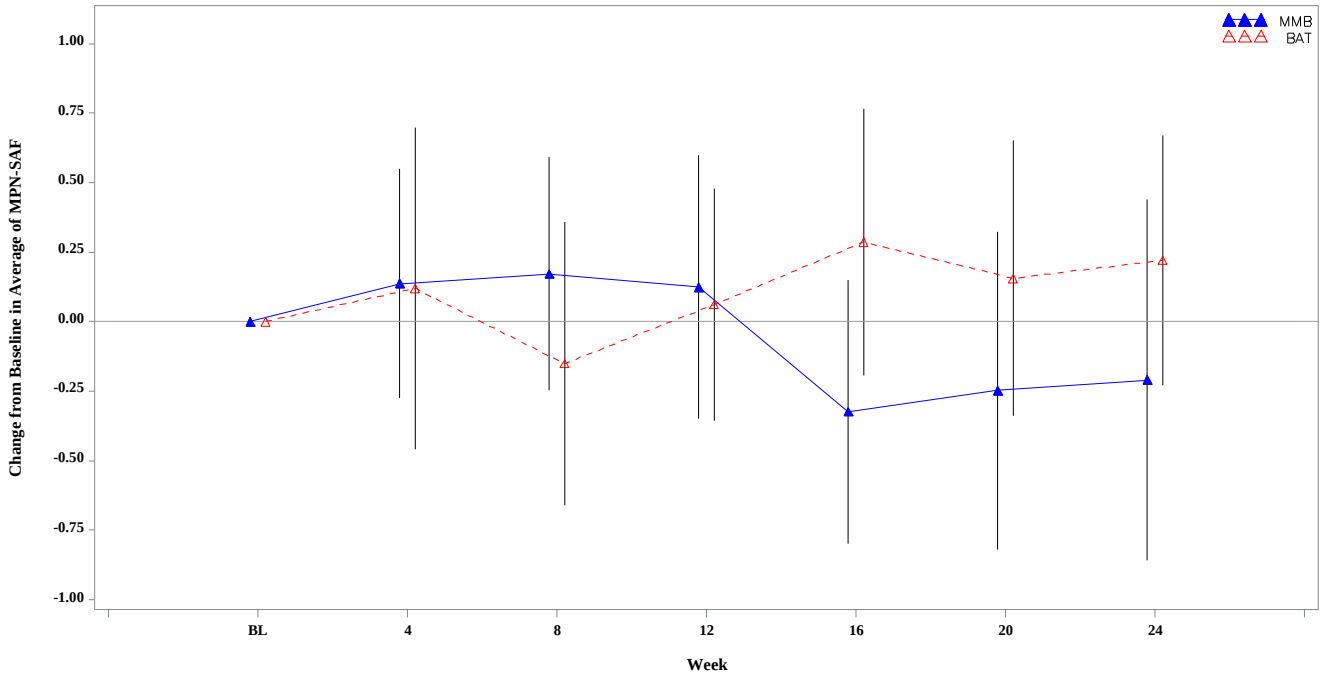


MMB	(n)	50	45	44	37	36	32	27
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF= Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-mpn-line-chg-rt.pdf 24AUG2023:16:52

Figure 2.3302: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Mean Symptom Score Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set



MMB (n)	50	45	44	37	36	32	27
BAT (n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF= Myeloproliferative Neoplasm Symptom Assessment Form

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-mpnsaf-line-chg-rt.pdf 24AUG2023:16:52

Table 2.7301: Analysis of MPN-SAF Mean Questionnaire Item #1 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0101 - Early Satiety at Baseline		
n	50	29
Mean (SD)	2.8 (2.80)	3.4 (3.28)
Median	2.0	3.0
Q1, Q3	0.0, 5.0	0.0, 6.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
MPN0101 - Early Satiety at Week 4		
n	60	31
Mean (SD)	2.7 (3.01)	3.4 (3.33)
Median	2.0	2.0
Q1, Q3	0.0, 4.5	0.0, 7.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in Early Satiety at Week 4 from Baseline		
n	45	26
Mean (SD)	0.1 (2.72)	0.2 (2.89)
Median	0.0	0.0
Q1, Q3	-1.0, 1.0	0.0, 0.0
Min, Max	-6.0, 9.0	-7.0, 8.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7301: Analysis of MPN-SAF Mean Questionnaire Item #1 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	47	27	
n [2]	45	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.08 [0.41] (-0.74, 0.89)		0.25 [0.49] (-0.72, 1.22)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.17 [0.63] (-1.43, 1.08)		
MMRM: P-value	0.79		
Corrected Hedges' g (95% CI)	-0.064 (-0.547, 0.419)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.49		
Percent Change in Early Satiety at Week 4 from Baseline			
n	31	17	
Mean (SD)	-14.3 (80.27)	4.9 (67.89)	
Median	-25.0	0.0	
Q1, Q3	-60.0, 14.3	-33.3, 0.0	
Min, Max	-100.0, 300.0	-100.0, 200.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	32	18	
n [2]	31	17	
MMRM: Least Squares Mean [SE] (95% CI)	-7.62 [16.27] (-40.40, 25.17)		4.82 [19.84] (-35.17, 44.80)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-12.43 [25.67] (-64.16, 39.30)		
MMRM: P-value	0.63		
Corrected Hedges' g (95% CI)	-0.140 (-0.732, 0.453)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.15		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7301: Analysis of MPN-SAF Mean Questionnaire Item #1 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0101 - Early Satiety at Week 8		
n	57	27
Mean (SD)	2.6 (2.83)	3.5 (2.78)
Median	2.0	4.0
Q1, Q3	0.0, 3.0	0.0, 5.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	86%	69%
Number of Subjects in Risk	61	36
Return Rate in Risk (%)	93%	75%
Change in Early Satiety at Week 8 from Baseline		
n	44	24
Mean (SD)	0.1 (2.67)	-0.1 (2.80)
Median	0.0	0.0
Q1, Q3	-1.5, 1.0	-0.5, 1.0
Min, Max	-7.0, 9.0	-7.0, 6.0
Difference in Change from Baseline at Week 8		
n [1]	47	27
n [2]	44	24
MMRM: Least Squares Mean [SE] (95% CI)	0.20 [0.41] (-0.62, 1.02)	0.35 [0.49] (-0.63, 1.34)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.15 [0.64] (-1.43, 1.12)	
MMRM: P-value	0.81	
Corrected Hedges' g (95% CI)	-0.058 (-0.555, 0.440)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.48	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7301: Analysis of MPN-SAF Mean Questionnaire Item #1 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Early Satiety at Week 8 from Baseline		
n	30	16
Mean (SD)	-5.7 (81.40)	10.4 (78.75)
Median	-18.1	0.0
Q1, Q3	-62.5, 28.6	-35.4, 33.3
Min, Max	-100.0, 200.0	-100.0, 250.0
Difference in Percent Change from Baseline at Week 8		
n [1]	32	18
n [2]	30	16
MMRM: Least Squares Mean [SE] (95% CI)	-8.86 [15.58] (-40.25, 22.53)	20.74 [19.06] (-17.68, 59.16)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-29.59 [24.50] (-78.98, 19.79)	
MMRM: P-value	0.23	
Corrected Hedges' g (95% CI)	-0.353 (-0.964, 0.258)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.32	
MPN0101 - Early Satiety at Week 12		
n	51	30
Mean (SD)	2.3 (2.44)	3.4 (3.01)
Median	2.0	4.0
Q1, Q3	0.0, 4.0	0.0, 5.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	77%	77%
Number of Subjects in Risk	59	33
Return Rate in Risk (%)	86%	91%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn01-rt.pdf 24AUG2023:16:59

Table 2.7301: Analysis of MPN-SAF Mean Questionnaire Item #1 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Early Satiety at Week 12 from Baseline		
n	37	26
Mean (SD)	-0.1 (2.32)	-0.1 (2.72)
Median	0.0	0.0
Q1, Q3	-1.0, 1.0	-2.0, 1.0
Min, Max	-7.0, 5.0	-7.0, 5.0
Difference in Change from Baseline at Week 12		
n [1]	47	27
n [2]	37	26
MMRM: Least Squares Mean [SE] (95% CI)	-0.07 [0.39] (-0.85, 0.71)	0.27 [0.44] (-0.61, 1.16)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.34 [0.59] (-1.51, 0.83)	
MMRM: P-value	0.56	
Corrected Hedges' g (95% CI)	-0.145 (-0.647, 0.357)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.33	
Percent Change in Early Satiety at Week 12 from Baseline		
n	25	17
Mean (SD)	0.3 (109.15)	-5.5 (71.66)
Median	-33.3	0.0
Q1, Q3	-66.7, 25.0	-42.9, 20.0
Min, Max	-100.0, 400.0	-100.0, 150.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7301: Analysis of MPN-SAF Mean Questionnaire Item #1 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 12			
n [1]	32	18	
n [2]	25	17	
MMRM: Least Squares Mean [SE] (95% CI)	0.12 [19.26] (-38.70, 38.95)		8.23 [23.96] (-40.05, 56.52)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-8.11 [30.72] (-70.03, 53.80)		
MMRM: P-value	0.79		
Corrected Hedges' g (95% CI)	-0.082 (-0.698, 0.535)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.36		
MPN0101 - Early Satiety at Week 16			
n	48	30	
Mean (SD)	2.4 (3.06)	3.3 (2.96)	
Median	1.0	3.5	
Q1, Q3	0.0, 4.5	0.0, 5.0	
Min, Max	0.0, 10.0	0.0, 8.0	
Return Rate (%)	73%	77%	
Number of Subjects in Risk	56	33	
Return Rate in Risk (%)	86%	91%	
Change in Early Satiety at Week 16 from Baseline			
n	36	26	
Mean (SD)	-0.1 (2.80)	0.2 (3.24)	
Median	0.0	0.0	
Q1, Q3	-1.5, 1.0	-2.0, 2.0	
Min, Max	-7.0, 9.0	-7.0, 8.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7301: Analysis of MPN-SAF Mean Questionnaire Item #1 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	47	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.20 [0.46] (-0.72, 1.12)	0.62 [0.53] (-0.44, 1.67)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.42 [0.70] (-1.81, 0.97)		
MMRM: P-value	0.55		
Corrected Hedges' g (95% CI)	-0.152 (-0.657, 0.354)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.32		
Percent Change in Early Satiety at Week 16 from Baseline			
n	24	17	
Mean (SD)	25.7 (213.58)	-1.6 (71.84)	
Median	-25.0	-20.0	
Q1, Q3	-100.0, 25.0	-33.3, 0.0	
Min, Max	-100.0, 900.0	-100.0, 166.7	
Difference in Percent Change from Baseline at Week 16			
n [1]	32	18	
n [2]	24	17	
MMRM: Least Squares Mean [SE] (95% CI)	16.95 [31.54] (-46.61, 80.52)	17.08 [39.05] (-61.61, 95.77)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.12 [50.18] (-101.26, 101.01)		
MMRM: P-value	1.00		
Corrected Hedges' g (95% CI)	-0.001 (-0.622, 0.621)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.18		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7301: Analysis of MPN-SAF Mean Questionnaire Item #1 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0101 - Early Satiety at Week 20		
n	44	29
Mean (SD)	2.0 (2.31)	3.5 (3.09)
Median	1.0	3.0
Q1, Q3	0.0, 3.5	0.0, 6.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	67%	74%
Number of Subjects in Risk	51	32
Return Rate in Risk (%)	86%	91%
Change in Early Satiety at Week 20 from Baseline		
n	32	24
Mean (SD)	-0.4 (2.21)	0.0 (3.54)
Median	0.0	0.0
Q1, Q3	-1.5, 1.0	-1.5, 1.5
Min, Max	-7.0, 5.0	-7.0, 10.0
Difference in Change from Baseline at Week 20		
n [1]	47	27
n [2]	32	24
MMRM: Least Squares Mean [SE] (95% CI)	-0.27 [0.41] (-1.10, 0.56)	0.49 [0.46] (-0.44, 1.41)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.76 [0.62] (-1.99, 0.47)	
MMRM: P-value	0.22	
Corrected Hedges' g (95% CI)	-0.323 (-0.856, 0.209)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.13	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7301: Analysis of MPN-SAF Mean Questionnaire Item #1 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in Early Satiety at Week 20 from Baseline			
n	21	17	
Mean (SD)	-34.1 (78.01)	-5.8 (57.07)	
Median	-50.0	-10.0	
Q1, Q3	-100.0, 0.0	-33.3, 0.0	
Min, Max	-100.0, 200.0	-100.0, 133.3	
Difference in Percent Change from Baseline at Week 20			
n [1]	32	18	
n [2]	21	17	
MMRM: Least Squares Mean [SE] (95% CI)	-34.63 [15.70] (-66.27, -2.98)	2.52 [16.82] (-31.39, 36.43)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-37.15 [23.06] (-83.62, 9.32)		
MMRM: P-value	0.11		
Corrected Hedges' g (95% CI)	-0.514 (-1.163, 0.136)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.020		
MPN0101 - Early Satiety at Week 24			
n	41	29	
Mean (SD)	2.1 (2.71)	3.7 (3.13)	
Median	1.0	3.0	
Q1, Q3	0.0, 3.0	1.0, 7.0	
Min, Max	0.0, 9.0	0.0, 9.0	
Return Rate (%)	62%	74%	
Number of Subjects in Risk	48	31	
Return Rate in Risk (%)	85%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7301: Analysis of MPN-SAF Mean Questionnaire Item #1 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Early Satiety at Week 24 from Baseline		
n	27	23
Mean (SD)	-0.4 (2.27)	-0.2 (2.79)
Median	0.0	0.0
Q1, Q3	-2.0, 1.0	-2.0, 1.0
Min, Max	-7.0, 4.0	-7.0, 5.0
Difference in Change from Baseline at Week 24		
n [1]	47	27
n [2]	27	23
MMRM: Least Squares Mean [SE] (95% CI)	-0.03 [0.44] (-0.91, 0.85)	0.79 [0.49] (-0.19, 1.77)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.82 [0.65] (-2.13, 0.49)	
MMRM: P-value	0.21	
Corrected Hedges' g (95% CI)	-0.348 (-0.909, 0.212)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.26	
Percent Change in Early Satiety at Week 24 from Baseline		
n	17	17
Mean (SD)	-29.0 (72.85)	6.2 (72.10)
Median	-40.0	0.0
Q1, Q3	-100.0, 14.3	-33.3, 33.3
Min, Max	-100.0, 100.0	-100.0, 150.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7301: Analysis of MPN-SAF Mean Questionnaire Item #1 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	32	18	
n [2]	17	17	
MMRM: Least Squares Mean [SE] (95% CI)	-16.01 [17.69] (-51.66, 19.63)	16.33 [19.18] (-22.34, 54.99)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-32.34 [26.08] (-84.91, 20.22)		
MMRM: P-value	0.22		
Corrected Hedges' g (95% CI)	-0.415 (-1.095, 0.264)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.094		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7302: Analysis of MPN-SAF Mean Questionnaire Item #2 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0102 - Abdominal Pain at Baseline		
n	50	29
Mean (SD)	2.2 (2.68)	3.0 (3.12)
Median	1.0	3.0
Q1, Q3	0.0, 4.0	0.0, 5.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
MPN0102 - Abdominal Pain at Week 4		
n	60	31
Mean (SD)	2.0 (2.19)	3.0 (3.20)
Median	1.0	2.0
Q1, Q3	0.0, 3.0	0.0, 7.0
Min, Max	0.0, 8.0	0.0, 10.0
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in Abdominal Pain at Week 4 from Baseline		
n	45	26
Mean (SD)	-0.1 (2.56)	-0.1 (1.96)
Median	0.0	0.0
Q1, Q3	-1.0, 1.0	-1.0, 1.0
Min, Max	-5.0, 7.0	-5.0, 4.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7302: Analysis of MPN-SAF Mean Questionnaire Item #2 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Change from Baseline at Week 4		
n [1]	47	27
n [2]	45	26
MMRM: Least Squares Mean [SE] (95% CI)	-0.27 [0.32] (-0.91, 0.37)	0.10 [0.38] (-0.66, 0.86)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.37 [0.49] (-1.35, 0.62)	
MMRM: P-value	0.46	
Corrected Hedges' g (95% CI)	-0.176 (-0.660, 0.308)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.53	
Percent Change in Abdominal Pain at Week 4 from Baseline		
n	25	16
Mean (SD)	-24.7 (51.58)	6.6 (74.28)
Median	-33.3	0.0
Q1, Q3	-57.1, 0.0	-41.7, 28.3
Min, Max	-100.0, 100.0	-100.0, 200.0
Difference in Percent Change from Baseline at Week 4		
n [1]	26	16
n [2]	25	16
MMRM: Least Squares Mean [SE] (95% CI)	-41.31 [13.23] (-68.13, -14.48)	3.52 [14.69] (-26.27, 33.31)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-44.83 [19.63] (-84.63, -5.02)	
MMRM: P-value	0.028	
Corrected Hedges' g (95% CI)	-0.693 (-1.339, -0.048)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.13	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7302: Analysis of MPN-SAF Mean Questionnaire Item #2 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0102 - Abdominal Pain at Week 8		
n	57	27
Mean (SD)	2.2 (2.62)	2.8 (2.82)
Median	1.0	2.0
Q1, Q3	0.0, 4.0	0.0, 5.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	86%	69%
Number of Subjects in Risk	61	36
Return Rate in Risk (%)	93%	75%
Change in Abdominal Pain at Week 8 from Baseline		
n	44	24
Mean (SD)	0.2 (2.90)	0.1 (2.02)
Median	0.0	0.0
Q1, Q3	-1.0, 1.0	0.0, 1.0
Min, Max	-7.0, 8.0	-5.0, 3.0
Difference in Change from Baseline at Week 8		
n [1]	47	27
n [2]	44	24
MMRM: Least Squares Mean [SE] (95% CI)	-0.03 [0.36] (-0.74, 0.69)	0.38 [0.44] (-0.50, 1.26)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.41 [0.57] (-1.54, 0.72)	
MMRM: P-value	0.47	
Corrected Hedges' g (95% CI)	-0.177 (-0.675, 0.322)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.29	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7302: Analysis of MPN-SAF Mean Questionnaire Item #2 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Abdominal Pain at Week 8 from Baseline		
n	24	13
Mean (SD)	14.9 (136.63)	6.1 (70.81)
Median	-20.5	0.0
Q1, Q3	-63.1, 45.0	-28.6, 14.3
Min, Max	-100.0, 500.0	-100.0, 200.0
Difference in Percent Change from Baseline at Week 8		
n [1]	26	16
n [2]	24	13
MMRM: Least Squares Mean [SE] (95% CI)	-3.82 [23.72] (-51.92, 44.29)	9.20 [29.82] (-51.28, 69.68)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-13.01 [38.09] (-90.27, 64.24)	
MMRM: P-value	0.73	
Corrected Hedges' g (95% CI)	-0.112 (-0.788, 0.563)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.26	
MPN0102 - Abdominal Pain at Week 12		
n	51	30
Mean (SD)	1.8 (2.10)	3.2 (2.95)
Median	1.0	3.0
Q1, Q3	0.0, 3.0	0.0, 5.0
Min, Max	0.0, 7.0	0.0, 10.0
Return Rate (%)	77%	77%
Number of Subjects in Risk	59	33
Return Rate in Risk (%)	86%	91%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn02-rt.pdf 24AUG2023:16:59

Table 2.7302: Analysis of MPN-SAF Mean Questionnaire Item #2 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Abdominal Pain at Week 12 from Baseline			
n	37	26	
Mean (SD)	-0.3 (2.23)	0.3 (2.28)	
Median	0.0	0.0	
Q1, Q3	-1.0, 0.0	0.0, 1.0	
Min, Max	-5.0, 5.0	-5.0, 5.0	
Difference in Change from Baseline at Week 12			
n [1]	47	27	
n [2]	37	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.32 [0.33] (-0.97, 0.33)	0.58 [0.38] (-0.18, 1.33)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.89 [0.49] (-1.88, 0.09)		
MMRM: P-value	0.074		
Corrected Hedges' g (95% CI)	-0.451 (-0.959, 0.057)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.13		
Percent Change in Abdominal Pain at Week 12 from Baseline			
n	21	15	
Mean (SD)	7.6 (103.47)	3.4 (69.98)	
Median	-14.3	0.0	
Q1, Q3	-50.0, 20.0	-40.0, 14.3	
Min, Max	-100.0, 300.0	-100.0, 200.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7302: Analysis of MPN-SAF Mean Questionnaire Item #2 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 12		
n [1]	26	16
n [2]	21	15
MMRM: Least Squares Mean [SE] (95% CI)	-13.00 [18.45] (-50.42, 24.41)	6.75 [21.95] (-37.77, 51.27)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-19.75 [28.57] (-77.69, 38.19)	
MMRM: P-value	0.49	
Corrected Hedges' g (95% CI)	-0.228 (-0.893, 0.437)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.16	
MPN0102 - Abdominal Pain at Week 16		
n	48	30
Mean (SD)	1.8 (2.01)	3.3 (3.24)
Median	1.0	3.0
Q1, Q3	0.0, 3.0	0.0, 6.0
Min, Max	0.0, 7.0	0.0, 10.0
Return Rate (%)	73%	77%
Number of Subjects in Risk	56	33
Return Rate in Risk (%)	86%	91%
Change in Abdominal Pain at Week 16 from Baseline		
n	36	26
Mean (SD)	-0.4 (2.36)	0.8 (3.10)
Median	0.0	0.0
Q1, Q3	-2.0, 1.0	0.0, 2.0
Min, Max	-6.0, 4.0	-7.0, 9.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7302: Analysis of MPN-SAF Mean Questionnaire Item #2 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	47	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.47 [0.37] (-1.20, 0.26)	1.02 [0.43] (0.17, 1.87)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.49 [0.56] (-2.60, -0.38)		
MMRM: P-value	0.009		
Corrected Hedges' g (95% CI)	-0.672 (-1.190, -0.154)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.025		
Percent Change in Abdominal Pain at Week 16 from Baseline			
n	20	15	
Mean (SD)	-4.0 (101.16)	0.1 (54.62)	
Median	-35.7	0.0	
Q1, Q3	-70.8, 45.0	-40.0, 25.0	
Min, Max	-100.0, 300.0	-100.0, 100.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	26	16	
n [2]	20	15	
MMRM: Least Squares Mean [SE] (95% CI)	-23.01 [17.32] (-58.13, 12.12)	2.38 [20.30] (-38.78, 43.55)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-25.39 [26.55] (-79.24, 28.46)		
MMRM: P-value	0.35		
Corrected Hedges' g (95% CI)	-0.318 (-0.992, 0.355)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.067		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.7302: Analysis of MPN-SAF Mean Questionnaire Item #2 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0102 - Abdominal Pain at Week 20		
n	44	29
Mean (SD)	1.3 (1.73)	3.3 (3.12)
Median	0.0	3.0
Q1, Q3	0.0, 2.0	1.0, 5.0
Min, Max	0.0, 7.0	0.0, 10.0
Return Rate (%)	67%	74%
Number of Subjects in Risk	51	32
Return Rate in Risk (%)	86%	91%
Change in Abdominal Pain at Week 20 from Baseline		
n	32	24
Mean (SD)	-0.8 (2.36)	0.6 (2.73)
Median	0.0	1.0
Q1, Q3	-2.5, 0.0	-0.5, 2.0
Min, Max	-6.0, 3.0	-5.0, 5.0
Difference in Change from Baseline at Week 20		
n [1]	47	27
n [2]	32	24
MMRM: Least Squares Mean [SE] (95% CI)	-0.73 [0.33] (-1.40, -0.06)	0.93 [0.38] (0.16, 1.69)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.65 [0.50] (-2.66, -0.65)	
MMRM: P-value	0.002	
Corrected Hedges' g (95% CI)	-0.866 (-1.420, -0.313)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.003	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn02-rt.pdf 24AUG2023:16:59

Table 2.7302: Analysis of MPN-SAF Mean Questionnaire Item #2 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Abdominal Pain at Week 20 from Baseline		
n	17	14
Mean (SD)	-15.3 (113.63)	6.0 (75.73)
Median	-50.0	0.0
Q1, Q3	-85.7, 0.0	-50.0, 28.6
Min, Max	-100.0, 300.0	-100.0, 200.0
Difference in Percent Change from Baseline at Week 20		
n [1]	26	16
n [2]	17	14
MMRM: Least Squares Mean [SE] (95% CI)	-28.36 [18.53] (-65.94, 9.22)	9.59 [22.09] (-35.20, 54.38)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-37.95 [28.74] (-96.25, 20.35)	
MMRM: P-value	0.20	
Corrected Hedges' g (95% CI)	-0.466 (-1.183, 0.251)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.010	
MPN0102 - Abdominal Pain at Week 24		
n	41	29
Mean (SD)	1.7 (2.38)	3.4 (3.69)
Median	1.0	2.0
Q1, Q3	0.0, 2.0	0.0, 7.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	62%	74%
Number of Subjects in Risk	48	31
Return Rate in Risk (%)	85%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn02-rt.pdf 24AUG2023:16:59

Table 2.7302: Analysis of MPN-SAF Mean Questionnaire Item #2 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Abdominal Pain at Week 24 from Baseline			
n	27	23	
Mean (SD)	-0.4 (2.19)	0.4 (1.90)	
Median	0.0	0.0	
Q1, Q3	-2.0, 0.0	0.0, 2.0	
Min, Max	-5.0, 5.0	-5.0, 4.0	
Difference in Change from Baseline at Week 24			
n [1]	47	27	
n [2]	27	23	
MMRM: Least Squares Mean [SE] (95% CI)	-0.15 [0.39] (-0.92, 0.62)		0.75 [0.43] (-0.11, 1.61)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.90 [0.57] (-2.05, 0.25)		
MMRM: P-value	0.12		
Corrected Hedges' g (95% CI)	-0.435 (-0.998, 0.128)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.030		
Percent Change in Abdominal Pain at Week 24 from Baseline			
n	15	14	
Mean (SD)	9.5 (153.43)	-5.1 (51.19)	
Median	-42.9	0.0	
Q1, Q3	-83.3, 0.0	-25.0, 28.6	
Min, Max	-100.0, 500.0	-100.0, 75.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7302: Analysis of MPN-SAF Mean Questionnaire Item #2 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	26	16	
n [2]	15	14	
MMRM: Least Squares Mean [SE] (95% CI)	-14.14 [25.52] (-65.90, 37.63)		-6.44 [28.65] (-64.53, 51.66)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-7.70 [38.17] (-85.10, 69.71)		
MMRM: P-value	0.84		
Corrected Hedges' g (95% CI)	-0.073 (-0.801, 0.656)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.17		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7303: Analysis of MPN-SAF Mean Questionnaire Item #3 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0103 - Abdominal Discomfort at Baseline		
n	50	29
Mean (SD)	2.5 (2.71)	3.8 (3.10)
Median	1.0	3.0
Q1, Q3	0.0, 4.0	1.0, 7.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
MPN0103 - Abdominal Discomfort at Week 4		
n	60	31
Mean (SD)	2.4 (2.51)	3.4 (3.26)
Median	2.0	2.0
Q1, Q3	0.0, 4.0	0.0, 7.0
Min, Max	0.0, 8.0	0.0, 10.0
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in Abdominal Discomfort at Week 4 from Baseline		
n	45	26
Mean (SD)	0.2 (2.57)	-0.4 (2.50)
Median	0.0	0.0
Q1, Q3	-1.0, 1.0	-1.0, 1.0
Min, Max	-6.0, 7.0	-8.0, 4.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn03-rt.pdf 24AUG2023:17:00

Table 2.7303: Analysis of MPN-SAF Mean Questionnaire Item #3 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	47	27	
n [2]	45	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.26 [0.36] (-0.97, 0.45)	0.07 [0.44] (-0.80, 0.94)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.33 [0.56] (-1.45, 0.79)		
MMRM: P-value	0.56		
Corrected Hedges' g (95% CI)	-0.140 (-0.623, 0.344)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.99		
Percent Change in Abdominal Discomfort at Week 4 from Baseline			
n	30	19	
Mean (SD)	26.4 (164.26)	-5.5 (86.51)	
Median	-16.7	-20.0	
Q1, Q3	-57.1, 25.0	-50.0, 14.3	
Min, Max	-100.0, 700.0	-100.0, 300.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	31	20	
n [2]	30	19	
MMRM: Least Squares Mean [SE] (95% CI)	6.61 [26.46] (-46.68, 59.90)	-0.53 [31.36] (-63.69, 62.64)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	7.14 [40.96] (-75.36, 89.64)		
MMRM: P-value	0.86		
Corrected Hedges' g (95% CI)	0.050 (-0.525, 0.624)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.69		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7303: Analysis of MPN-SAF Mean Questionnaire Item #3 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0103 - Abdominal Discomfort at Week 8		
n	57	27
Mean (SD)	2.3 (2.70)	3.0 (2.86)
Median	1.0	3.0
Q1, Q3	0.0, 4.0	0.0, 5.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	86%	69%
Number of Subjects in Risk	61	36
Return Rate in Risk (%)	93%	75%
Change in Abdominal Discomfort at Week 8 from Baseline		
n	44	24
Mean (SD)	0.1 (2.93)	-0.4 (2.63)
Median	0.0	0.0
Q1, Q3	-1.0, 1.5	-3.0, 1.0
Min, Max	-8.0, 8.0	-5.0, 5.0
Difference in Change from Baseline at Week 8		
n [1]	47	27
n [2]	44	24
MMRM: Least Squares Mean [SE] (95% CI)	-0.27 [0.39] (-1.05, 0.50)	0.03 [0.49] (-0.94, 0.99)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.30 [0.62] (-1.53, 0.93)	
MMRM: P-value	0.63	
Corrected Hedges' g (95% CI)	-0.118 (-0.616, 0.380)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.86	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn03-rt.pdf 24AUG2023:17:00

Table 2.7303: Analysis of MPN-SAF Mean Questionnaire Item #3 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Abdominal Discomfort at Week 8 from Baseline		
n	29	17
Mean (SD)	41.3 (201.67)	0.4 (99.77)
Median	-25.0	-28.6
Q1, Q3	-100.0, 50.0	-42.9, 11.1
Min, Max	-100.0, 800.0	-100.0, 300.0
Difference in Percent Change from Baseline at Week 8		
n [1]	31	20
n [2]	29	17
MMRM: Least Squares Mean [SE] (95% CI)	16.22 [31.33] (-46.88, 79.31)	-0.46 [37.86] (-76.71, 75.80)
MMRM: Least Squares Mean Difference [SE] (95% CI)	16.67 [49.17] (-82.36, 115.71)	
MMRM: P-value	0.74	
Corrected Hedges' g (95% CI)	0.100 (-0.499, 0.699)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.76	
MPN0103 - Abdominal Discomfort at Week 12		
n	51	30
Mean (SD)	1.9 (2.21)	3.6 (2.92)
Median	1.0	3.0
Q1, Q3	0.0, 3.0	1.0, 6.0
Min, Max	0.0, 8.0	0.0, 10.0
Return Rate (%)	77%	77%
Number of Subjects in Risk	59	33
Return Rate in Risk (%)	86%	91%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7303: Analysis of MPN-SAF Mean Questionnaire Item #3 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Abdominal Discomfort at Week 12 from Baseline			
n	37	26	
Mean (SD)	-0.3 (2.36)	-0.1 (2.50)	
Median	0.0	0.0	
Q1, Q3	-2.0, 1.0	-1.0, 1.0	
Min, Max	-5.0, 6.0	-5.0, 5.0	
Difference in Change from Baseline at Week 12			
n [1]	47	27	
n [2]	37	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.60 [0.34] (-1.28, 0.09)	0.28 [0.40] (-0.52, 1.08)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.88 [0.52] (-1.92, 0.16)		
MMRM: P-value	0.097		
Corrected Hedges' g (95% CI)	-0.419 (-0.926, 0.088)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.21		
Percent Change in Abdominal Discomfort at Week 12 from Baseline			
n	25	19	
Mean (SD)	14.8 (142.63)	2.7 (89.89)	
Median	-33.3	-16.7	
Q1, Q3	-55.6, 20.0	-40.0, 11.1	
Min, Max	-100.0, 500.0	-100.0, 300.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7303: Analysis of MPN-SAF Mean Questionnaire Item #3 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 12			
n [1]	31	20	
n [2]	25	19	
MMRM: Least Squares Mean [SE] (95% CI)	12.02 [29.39] (-47.18, 71.23)		1.63 [34.93] (-68.72, 71.98)
MMRM: Least Squares Mean Difference [SE] (95% CI)	10.39 [45.54] (-81.32, 102.10)		
MMRM: P-value	0.82		
Corrected Hedges' g (95% CI)	0.068 (-0.528, 0.665)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.36		
MPN0103 - Abdominal Discomfort at Week 16			
n	48	30	
Mean (SD)	1.9 (2.18)	3.5 (3.24)	
Median	1.0	3.0	
Q1, Q3	0.0, 4.0	0.0, 6.0	
Min, Max	0.0, 8.0	0.0, 10.0	
Return Rate (%)	73%	77%	
Number of Subjects in Risk	56	33	
Return Rate in Risk (%)	86%	91%	
Change in Abdominal Discomfort at Week 16 from Baseline			
n	36	26	
Mean (SD)	-0.5 (2.32)	0.2 (2.70)	
Median	0.0	0.0	
Q1, Q3	-2.0, 1.0	-1.0, 1.0	
Min, Max	-5.0, 4.0	-6.0, 5.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7303: Analysis of MPN-SAF Mean Questionnaire Item #3 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	47	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.79 [0.37] (-1.52, -0.06)	0.61 [0.42] (-0.24, 1.46)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.40 [0.55] (-2.51, -0.29)		
MMRM: P-value	0.014		
Corrected Hedges' g (95% CI)	-0.634 (-1.151, -0.117)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.15		
Percent Change in Abdominal Discomfort at Week 16 from Baseline			
n	24	19	
Mean (SD)	6.4 (134.57)	13.1 (114.20)	
Median	-41.7	0.0	
Q1, Q3	-91.7, 25.0	-50.0, 14.3	
Min, Max	-100.0, 400.0	-100.0, 400.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	31	20	
n [2]	24	19	
MMRM: Least Squares Mean [SE] (95% CI)	2.50 [29.92] (-57.75, 62.76)	12.04 [35.49] (-59.43, 83.51)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-9.54 [46.31] (-102.81, 83.72)		
MMRM: P-value	0.84		
Corrected Hedges' g (95% CI)	-0.062 (-0.664, 0.540)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.46		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7303: Analysis of MPN-SAF Mean Questionnaire Item #3 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0103 - Abdominal Discomfort at Week 20		
n	44	29
Mean (SD)	1.5 (1.80)	3.6 (3.16)
Median	1.0	3.0
Q1, Q3	0.0, 2.5	0.0, 5.0
Min, Max	0.0, 7.0	0.0, 10.0
Return Rate (%)	67%	74%
Number of Subjects in Risk	51	32
Return Rate in Risk (%)	86%	91%
Change in Abdominal Discomfort at Week 20 from Baseline		
n	32	24
Mean (SD)	-0.8 (2.25)	0.1 (2.38)
Median	-0.5	0.0
Q1, Q3	-2.0, 1.0	-1.0, 1.0
Min, Max	-6.0, 3.0	-5.0, 4.0
Difference in Change from Baseline at Week 20		
n [1]	47	27
n [2]	32	24
MMRM: Least Squares Mean [SE] (95% CI)	-0.99 [0.33] (-1.64, -0.34)	0.55 [0.36] (-0.18, 1.28)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.54 [0.48] (-2.50, -0.58)	
MMRM: P-value	0.002	
Corrected Hedges' g (95% CI)	-0.835 (-1.387, -0.284)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.023	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7303: Analysis of MPN-SAF Mean Questionnaire Item #3 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Abdominal Discomfort at Week 20 from Baseline		
n	20	18
Mean (SD)	-22.5 (101.96)	10.5 (71.85)
Median	-50.0	5.6
Q1, Q3	-100.0, -18.8	-40.0, 33.3
Min, Max	-100.0, 200.0	-100.0, 200.0
Difference in Percent Change from Baseline at Week 20		
n [1]	31	20
n [2]	20	18
MMRM: Least Squares Mean [SE] (95% CI)	-22.24 [22.16] (-66.87, 22.40)	6.52 [25.36] (-44.57, 57.61)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-28.76 [33.44] (-96.11, 38.60)	
MMRM: P-value	0.39	
Corrected Hedges' g (95% CI)	-0.273 (-0.912, 0.367)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.006	
MPN0103 - Abdominal Discomfort at Week 24		
n	41	29
Mean (SD)	1.5 (2.13)	3.7 (3.45)
Median	1.0	3.0
Q1, Q3	0.0, 2.0	0.0, 7.0
Min, Max	0.0, 7.0	0.0, 10.0
Return Rate (%)	62%	74%
Number of Subjects in Risk	48	31
Return Rate in Risk (%)	85%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7303: Analysis of MPN-SAF Mean Questionnaire Item #3 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Abdominal Discomfort at Week 24 from Baseline			
n	27	23	
Mean (SD)	-0.6 (2.17)	0.4 (2.23)	
Median	0.0	0.0	
Q1, Q3	-2.0, 1.0	-1.0, 2.0	
Min, Max	-5.0, 5.0	-4.0, 6.0	
Difference in Change from Baseline at Week 24			
n [1]	47	27	
n [2]	27	23	
MMRM: Least Squares Mean [SE] (95% CI)	-0.69 [0.38] (-1.44, 0.07)	0.79 [0.42] (-0.05, 1.63)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.47 [0.56] (-2.59, -0.35)		
MMRM: P-value	0.011		
Corrected Hedges' g (95% CI)	-0.728 (-1.302, -0.154)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.021		
Percent Change in Abdominal Discomfort at Week 24 from Baseline			
n	17	17	
Mean (SD)	-3.7 (145.25)	10.8 (82.18)	
Median	-50.0	0.0	
Q1, Q3	-100.0, 0.0	-33.3, 28.6	
Min, Max	-100.0, 500.0	-100.0, 200.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7303: Analysis of MPN-SAF Mean Questionnaire Item #3 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	**31**	**20**	
n [2]	**17**	**17**	
MMRM: Least Squares Mean [SE] (95% CI)	**-19.62 [24.36] (-68.68, 29.45)**	**8.06 [27.66] (-47.66, 63.77)**	
MMRM: Least Squares Mean Difference [SE] (95% CI)	**-27.67 [36.59] (-101.36, 46.02)**		
MMRM: P-value	**0.45**		
Corrected Hedges' g (95% CI)	**-0.251 (-0.926, 0.423)**		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	**0.035**		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

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Table 2.7304: Analysis of MPN-SAF Mean Questionnaire Item #4 Score and Change from Baseline

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0104 - Inactivity at Baseline		
n	50	29
Mean (SD)	3.6 (2.85)	4.2 (3.35)
Median	3.5	4.0
Q1, Q3	1.0, 6.0	0.0, 7.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
MPN0104 - Inactivity at Week 4		
n	60	31
Mean (SD)	3.6 (2.71)	4.5 (3.16)
Median	3.0	5.0
Q1, Q3	1.0, 5.0	1.0, 7.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in Inactivity at Week 4 from Baseline		
n	45	26
Mean (SD)	0.3 (2.28)	0.2 (2.53)
Median	0.0	0.0
Q1, Q3	-1.0, 1.0	-1.0, 1.0
Min, Max	-5.0, 5.0	-3.0, 7.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7304: Analysis of MPN-SAF Mean Questionnaire Item #4 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	47	27	
n [2]	45	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.44 [0.33] (-0.22, 1.09)	0.32 [0.38] (-0.45, 1.09)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.12 [0.50] (-0.88, 1.12)		
MMRM: P-value	0.82		
Corrected Hedges' g (95% CI)	0.055 (-0.428, 0.538)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.21		
Percent Change in Inactivity at Week 4 from Baseline			
n	38	18	
Mean (SD)	-0.8 (49.95)	-14.0 (47.21)	
Median	0.0	-16.3	
Q1, Q3	-33.3, 16.7	-33.3, 0.0	
Min, Max	-100.0, 150.0	-100.0, 100.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	39	19	
n [2]	38	18	
MMRM: Least Squares Mean [SE] (95% CI)	8.38 [8.30] (-8.28, 25.03)	-7.91 [10.76] (-29.50, 13.68)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	16.29 [13.70] (-11.21, 43.79)		
MMRM: P-value	0.24		
Corrected Hedges' g (95% CI)	0.325 (-0.240, 0.889)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.011		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7304: Analysis of MPN-SAF Mean Questionnaire Item #4 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
MPN0104 - Inactivity at Week 8			
n	57	27	
Mean (SD)	3.9 (2.79)	4.5 (2.50)	
Median	3.0	5.0	
Q1, Q3	2.0, 6.0	3.0, 6.0	
Min, Max	0.0, 9.0	0.0, 10.0	
Return Rate (%)	86%	69%	
Number of Subjects in Risk	61	36	
Return Rate in Risk (%)	93%	75%	
Change in Inactivity at Week 8 from Baseline			
n	44	24	
Mean (SD)	0.7 (2.61)	0.1 (2.28)	
Median	0.0	0.0	
Q1, Q3	-1.0, 2.0	-2.0, 1.0	
Min, Max	-4.0, 8.0	-3.0, 7.0	
Difference in Change from Baseline at Week 8			
n [1]	47	27	
n [2]	44	24	
MMRM: Least Squares Mean [SE] (95% CI)	0.82 [0.36] (0.10, 1.53)	0.49 [0.43] (-0.38, 1.36)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.32 [0.56] (-0.79, 1.44)		
MMRM: P-value	0.56		
Corrected Hedges' g (95% CI)	0.140 (-0.358, 0.638)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.50		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7304: Analysis of MPN-SAF Mean Questionnaire Item #4 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in Inactivity at Week 8 from Baseline			
n	37	18	
Mean (SD)	52.0 (165.72)	-1.9 (40.87)	
Median	0.0	-12.5	
Q1, Q3	-12.5, 50.0	-28.6, 20.0	
Min, Max	-100.0, 800.0	-66.7, 100.0	
Difference in Percent Change from Baseline at Week 8			
n [1]	39	19	
n [2]	37	18	
MMRM: Least Squares Mean [SE] (95% CI)	57.06 [22.16] (12.61, 101.52)	2.47 [31.74] (-61.21, 66.16)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	54.59 [38.71] (-23.09, 132.27)		
MMRM: P-value	0.16		
Corrected Hedges' g (95% CI)	0.399 (-0.169, 0.968)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.29		
MPN0104 - Inactivity at Week 12			
n	51	30	
Mean (SD)	3.6 (2.56)	4.6 (2.93)	
Median	3.0	4.5	
Q1, Q3	1.0, 5.0	2.0, 7.0	
Min, Max	0.0, 8.0	0.0, 10.0	
Return Rate (%)	77%	77%	
Number of Subjects in Risk	59	33	
Return Rate in Risk (%)	86%	91%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn04-rt.pdf 24AUG2023:17:00

Table 2.7304: Analysis of MPN-SAF Mean Questionnaire Item #4 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Inactivity at Week 12 from Baseline			
n	37	26	
Mean (SD)	0.7 (2.50)	0.4 (2.35)	
Median	1.0	0.0	
Q1, Q3	-1.0, 3.0	-1.0, 1.0	
Min, Max	-5.0, 5.0	-4.0, 7.0	
Difference in Change from Baseline at Week 12			
n [1]	47	27	
n [2]	37	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.88 [0.37] (0.14, 1.61)	0.62 [0.42] (-0.22, 1.46)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.25 [0.56] (-0.86, 1.36)		
MMRM: P-value	0.65		
Corrected Hedges' g (95% CI)	0.114 (-0.388, 0.616)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.92		
Percent Change in Inactivity at Week 12 from Baseline			
n	30	18	
Mean (SD)	42.0 (106.37)	17.8 (100.48)	
Median	15.5	-5.6	
Q1, Q3	-20.0, 100.0	-25.0, 20.0	
Min, Max	-100.0, 400.0	-60.0, 400.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7304: Analysis of MPN-SAF Mean Questionnaire Item #4 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 12			
n [1]	39	19	
n [2]	30	18	
MMRM: Least Squares Mean [SE] (95% CI)	67.14 [22.46] (22.08, 112.21)		20.30 [31.44] (-42.79, 83.39)
MMRM: Least Squares Mean Difference [SE] (95% CI)	46.84 [38.64] (-30.70, 124.38)		
MMRM: P-value	0.23		
Corrected Hedges' g (95% CI)	0.363 (-0.226, 0.952)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.68		
MPN0104 - Inactivity at Week 16			
n	48	30	
Mean (SD)	3.2 (2.47)	4.2 (3.06)	
Median	3.0	4.0	
Q1, Q3	1.0, 5.0	2.0, 7.0	
Min, Max	0.0, 8.0	0.0, 10.0	
Return Rate (%)	73%	77%	
Number of Subjects in Risk	56	33	
Return Rate in Risk (%)	86%	91%	
Change in Inactivity at Week 16 from Baseline			
n	36	26	
Mean (SD)	-0.1 (2.45)	0.4 (2.59)	
Median	0.0	0.0	
Q1, Q3	-2.0, 1.0	-1.0, 1.0	
Min, Max	-6.0, 5.0	-3.0, 10.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7304: Analysis of MPN-SAF Mean Questionnaire Item #4 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	47	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.40 [0.39] (-0.38, 1.18)	0.62 [0.45] (-0.28, 1.52)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.22 [0.59] (-1.41, 0.96)		
MMRM: P-value	0.71		
Corrected Hedges' g (95% CI)	-0.094 (-0.599, 0.410)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.40		
Percent Change in Inactivity at Week 16 from Baseline			
n	30	18	
Mean (SD)	17.6 (112.91)	-7.1 (38.50)	
Median	-5.6	-11.8	
Q1, Q3	-42.9, 50.0	-25.0, 14.3	
Min, Max	-100.0, 500.0	-100.0, 75.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	39	19	
n [2]	30	18	
MMRM: Least Squares Mean [SE] (95% CI)	55.79 [22.32] (11.01, 100.57)	-2.42 [31.41] (-65.45, 60.61)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	58.22 [38.54] (-19.11, 135.55)		
MMRM: P-value	0.14		
Corrected Hedges' g (95% CI)	0.453 (-0.138, 1.044)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.99		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7304: Analysis of MPN-SAF Mean Questionnaire Item #4 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0104 - Inactivity at Week 20		
n	44	29
Mean (SD)	3.2 (2.30)	4.6 (3.22)
Median	3.0	5.0
Q1, Q3	1.5, 5.0	2.0, 7.0
Min, Max	0.0, 7.0	0.0, 10.0
Return Rate (%)	67%	74%
Number of Subjects in Risk	51	32
Return Rate in Risk (%)	86%	91%
Change in Inactivity at Week 20 from Baseline		
n	32	24
Mean (SD)	0.1 (2.56)	0.5 (2.83)
Median	0.0	0.0
Q1, Q3	-1.5, 1.0	-1.0, 1.0
Min, Max	-6.0, 5.0	-4.0, 10.0
Difference in Change from Baseline at Week 20		
n [1]	47	27
n [2]	32	24
MMRM: Least Squares Mean [SE] (95% CI)	0.72 [0.40] (-0.08, 1.51)	0.65 [0.46] (-0.26, 1.56)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.07 [0.60] (-1.14, 1.27)	
MMRM: P-value	0.91	
Corrected Hedges' g (95% CI)	0.030 (-0.499, 0.560)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.54	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7304: Analysis of MPN-SAF Mean Questionnaire Item #4 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in Inactivity at Week 20 from Baseline			
n	27	17	
Mean (SD)	28.6 (127.13)	10.2 (79.85)	
Median	0.0	-10.0	
Q1, Q3	-40.0, 50.0	-20.0, 14.3	
Min, Max	-100.0, 500.0	-66.7, 300.0	
Difference in Percent Change from Baseline at Week 20			
n [1]	39	19	
n [2]	27	17	
MMRM: Least Squares Mean [SE] (95% CI)	66.56 [25.99] (14.41, 118.72)	10.36 [36.83] (-63.55, 84.26)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	56.21 [45.07] (-34.23, 146.65)		
MMRM: P-value	0.22		
Corrected Hedges' g (95% CI)	0.390 (-0.223, 1.002)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.76		
MPN0104 - Inactivity at Week 24			
n	41	29	
Mean (SD)	3.0 (2.64)	4.9 (3.24)	
Median	3.0	5.0	
Q1, Q3	1.0, 5.0	3.0, 7.0	
Min, Max	0.0, 9.0	0.0, 10.0	
Return Rate (%)	62%	74%	
Number of Subjects in Risk	48	31	
Return Rate in Risk (%)	85%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7304: Analysis of MPN-SAF Mean Questionnaire Item #4 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Inactivity at Week 24 from Baseline		
n	27	23
Mean (SD)	-0.3 (2.84)	1.0 (2.75)
Median	0.0	1.0
Q1, Q3	-2.0, 2.0	0.0, 1.0
Min, Max	-6.0, 6.0	-2.0, 10.0
Difference in Change from Baseline at Week 24		
n [1]	47	27
n [2]	27	23
MMRM: Least Squares Mean [SE] (95% CI)	0.19 [0.43] (-0.68, 1.05)	1.20 [0.48] (0.24, 2.15)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.01 [0.64] (-2.29, 0.27)	
MMRM: P-value	0.12	
Corrected Hedges' g (95% CI)	-0.438 (-1.000, 0.125)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.056	
Percent Change in Inactivity at Week 24 from Baseline		
n	23	16
Mean (SD)	14.2 (142.25)	15.3 (37.95)
Median	0.0	6.3
Q1, Q3	-57.1, 33.3	-11.8, 36.7
Min, Max	-100.0, 600.0	-33.3, 100.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7304: Analysis of MPN-SAF Mean Questionnaire Item #4 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	39	19	
n [2]	23	16	
MMRM: Least Squares Mean [SE] (95% CI)	47.99 [26.09] (-4.37, 100.35)	16.36 [36.46] (-56.80, 89.53)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	31.62 [44.84] (-58.35, 121.60)		
MMRM: P-value	0.48		
Corrected Hedges' g (95% CI)	0.231 (-0.409, 0.871)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.091		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7305: Analysis of MPN-SAF Mean Questionnaire Item #5 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0105 - Headaches at Baseline		
n	50	29
Mean (SD)	1.3 (2.22)	1.9 (2.78)
Median	0.0	1.0
Q1, Q3	0.0, 2.0	0.0, 2.0
Min, Max	0.0, 7.0	0.0, 10.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
MPN0105 - Headaches at Week 4		
n	60	31
Mean (SD)	1.0 (2.01)	1.9 (2.68)
Median	0.0	1.0
Q1, Q3	0.0, 1.0	0.0, 2.0
Min, Max	0.0, 9.0	0.0, 9.0
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in Headaches at Week 4 from Baseline		
n	45	26
Mean (SD)	-0.1 (2.19)	0.2 (2.47)
Median	0.0	0.0
Q1, Q3	0.0, 0.0	-1.0, 1.0
Min, Max	-7.0, 4.0	-5.0, 8.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7305: Analysis of MPN-SAF Mean Questionnaire Item #5 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	47	27	
n [2]	45	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.15 [0.31] (-0.77, 0.48)	0.32 [0.39] (-0.46, 1.09)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.46 [0.50] (-1.46, 0.53)		
MMRM: P-value	0.36		
Corrected Hedges' g (95% CI)	-0.222 (-0.707, 0.262)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.46		
Percent Change in Headaches at Week 4 from Baseline			
n	16	14	
Mean (SD)	-23.1 (95.98)	65.7 (262.82)	
Median	-58.3	-33.3	
Q1, Q3	-100.0, 25.0	-100.0, 100.0	
Min, Max	-100.0, 200.0	-100.0, 800.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	17	14	
n [2]	16	14	
MMRM: Least Squares Mean [SE] (95% CI)	-10.77 [51.92] (-117.71, 96.17)	71.47 [51.74] (-35.08, 178.02)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-82.24 [71.09] (-228.64, 64.17)		
MMRM: P-value	0.26		
Corrected Hedges' g (95% CI)	-0.398 (-1.122, 0.327)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.68		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7305: Analysis of MPN-SAF Mean Questionnaire Item #5 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
MPN0105 - Headaches at Week 8			
n	57	27	
Mean (SD)	1.3 (1.73)	1.2 (1.93)	
Median	1.0	0.0	
Q1, Q3	0.0, 2.0	0.0, 2.0	
Min, Max	0.0, 7.0	0.0, 6.0	
Return Rate (%)	86%	69%	
Number of Subjects in Risk	61	36	
Return Rate in Risk (%)	93%	75%	
Change in Headaches at Week 8 from Baseline			
n	44	24	
Mean (SD)	0.0 (1.92)	-0.5 (1.74)	
Median	0.0	0.0	
Q1, Q3	0.0, 1.0	-1.0, 0.5	
Min, Max	-6.0, 4.0	-5.0, 2.0	
Difference in Change from Baseline at Week 8			
n [1]	47	27	
n [2]	44	24	
MMRM: Least Squares Mean [SE] (95% CI)	0.01 [0.24] (-0.46, 0.49)	-0.33 [0.29] (-0.91, 0.24)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.35 [0.37] (-0.39, 1.09)		
MMRM: P-value	0.35		
Corrected Hedges' g (95% CI)	0.224 (-0.275, 0.723)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.27		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn05-rt.pdf 24AUG2023:17:00

Table 2.7305: Analysis of MPN-SAF Mean Questionnaire Item #5 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in Headaches at Week 8 from Baseline			
n	16	13	
Mean (SD)	-9.7 (87.68)	-11.6 (97.01)	
Median	-32.1	-40.0	
Q1, Q3	-77.4, 33.3	-100.0, 33.3	
Min, Max	-100.0, 200.0	-100.0, 200.0	
Difference in Percent Change from Baseline at Week 8			
n [1]	17	14	
n [2]	16	13	
MMRM: Least Squares Mean [SE] (95% CI)		14.43 [31.59] (-50.63, 79.49)	-5.23 [27.07] (-60.99, 50.53)
MMRM: Least Squares Mean Difference [SE] (95% CI)		19.66 [37.16] (-56.87, 96.19)	
MMRM: P-value		0.60	
Corrected Hedges' g (95% CI)		0.167 (-0.566, 0.900)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value		0.64	
MPN0105 - Headaches at Week 12			
n	51	30	
Mean (SD)	1.0 (1.90)	1.3 (2.17)	
Median	0.0	0.0	
Q1, Q3	0.0, 1.0	0.0, 2.0	
Min, Max	0.0, 8.0	0.0, 8.0	
Return Rate (%)	77%	77%	
Number of Subjects in Risk	59	33	
Return Rate in Risk (%)	86%	91%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7305: Analysis of MPN-SAF Mean Questionnaire Item #5 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Headaches at Week 12 from Baseline			
n	37	26	
Mean (SD)	-0.2 (2.43)	-0.4 (2.39)	
Median	0.0	0.0	
Q1, Q3	0.0, 0.0	-1.0, 0.0	
Min, Max	-7.0, 8.0	-5.0, 7.0	
Difference in Change from Baseline at Week 12			
n [1]	47	27	
n [2]	37	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.22 [0.32] (-0.87, 0.42)	-0.31 [0.38] (-1.06, 0.45)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.08 [0.50] (-0.90, 1.07)		
MMRM: P-value	0.87		
Corrected Hedges' g (95% CI)	0.042 (-0.459, 0.544)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.51		
Percent Change in Headaches at Week 12 from Baseline			
n	13	13	
Mean (SD)	-39.7 (74.58)	16.2 (217.49)	
Median	-85.7	-50.0	
Q1, Q3	-100.0, 16.7	-100.0, 0.0	
Min, Max	-100.0, 100.0	-100.0, 700.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7305: Analysis of MPN-SAF Mean Questionnaire Item #5 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 12		
n [1]	17	14
n [2]	13	13
MMRM: Least Squares Mean [SE] (95% CI)	-14.66 [45.18] (-107.72, 78.40)	23.84 [43.72] (-66.21, 113.89)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-38.50 [60.26] (-162.61, 85.61)	
MMRM: P-value	0.53	
Corrected Hedges' g (95% CI)	-0.233 (-1.004, 0.539)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.68	
MPN0105 - Headaches at Week 16		
n	48	30
Mean (SD)	1.1 (1.83)	1.4 (2.53)
Median	0.0	0.0
Q1, Q3	0.0, 1.0	0.0, 2.0
Min, Max	0.0, 7.0	0.0, 10.0
Return Rate (%)	73%	77%
Number of Subjects in Risk	56	33
Return Rate in Risk (%)	86%	91%
Change in Headaches at Week 16 from Baseline		
n	36	26
Mean (SD)	-0.1 (1.76)	-0.2 (2.03)
Median	0.0	0.0
Q1, Q3	-0.5, 0.0	-1.0, 0.0
Min, Max	-5.0, 7.0	-5.0, 5.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7305: Analysis of MPN-SAF Mean Questionnaire Item #5 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	47	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.31 [0.29] (-0.89, 0.26)	-0.04 [0.33] (-0.69, 0.62)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.27 [0.43] (-1.14, 0.59)		
MMRM: P-value	0.53		
Corrected Hedges' g (95% CI)	-0.159 (-0.664, 0.346)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.55		
Percent Change in Headaches at Week 16 from Baseline			
n	13	13	
Mean (SD)	-32.8 (60.55)	-8.5 (148.53)	
Median	-50.0	-66.7	
Q1, Q3	-83.3, 0.0	-100.0, 0.0	
Min, Max	-100.0, 100.0	-100.0, 400.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	17	14	
n [2]	13	13	
MMRM: Least Squares Mean [SE] (95% CI)	-18.54 [34.08] (-88.74, 51.65)	-1.52 [30.10] (-63.52, 60.48)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-17.03 [41.67] (-102.85, 68.79)		
MMRM: P-value	0.69		
Corrected Hedges' g (95% CI)	-0.142 (-0.912, 0.628)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.76		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7305: Analysis of MPN-SAF Mean Questionnaire Item #5 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0105 - Headaches at Week 20		
n	44	29
Mean (SD)	1.0 (2.13)	1.6 (2.41)
Median	0.0	0.0
Q1, Q3	0.0, 1.0	0.0, 3.0
Min, Max	0.0, 10.0	0.0, 7.0
Return Rate (%)	67%	74%
Number of Subjects in Risk	51	32
Return Rate in Risk (%)	86%	91%
Change in Headaches at Week 20 from Baseline		
n	32	24
Mean (SD)	0.3 (2.72)	-0.1 (2.67)
Median	0.0	0.0
Q1, Q3	-0.5, 0.0	-1.5, 1.0
Min, Max	-7.0, 10.0	-5.0, 6.0
Difference in Change from Baseline at Week 20		
n [1]	47	27
n [2]	32	24
MMRM: Least Squares Mean [SE] (95% CI)	-0.22 [0.40] (-1.02, 0.57)	0.03 [0.46] (-0.89, 0.96)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.26 [0.61] (-1.47, 0.96)	
MMRM: P-value	0.68	
Corrected Hedges' g (95% CI)	-0.112 (-0.641, 0.418)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.31	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7305: Analysis of MPN-SAF Mean Questionnaire Item #5 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Headaches at Week 20 from Baseline		
n	10	12
Mean (SD)	-41.0 (98.79)	42.0 (211.21)
Median	-100.0	-47.8
Q1, Q3	-100.0, -16.7	-100.0, 75.0
Min, Max	-100.0, 200.0	-100.0, 600.0
Difference in Percent Change from Baseline at Week 20		
n [1]	17	14
n [2]	10	12
MMRM: Least Squares Mean [SE] (95% CI)	-22.69 [43.63] (-112.55, 67.17)	37.81 [41.51] (-47.67, 123.30)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-60.50 [57.46] (-178.85, 57.84)	
MMRM: P-value	0.30	
Corrected Hedges' g (95% CI)	-0.412 (-1.260, 0.436)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.53	
MPN0105 - Headaches at Week 24		
n	41	29
Mean (SD)	0.8 (1.86)	1.2 (2.20)
Median	0.0	0.0
Q1, Q3	0.0, 0.0	0.0, 1.0
Min, Max	0.0, 8.0	0.0, 8.0
Return Rate (%)	62%	74%
Number of Subjects in Risk	48	31
Return Rate in Risk (%)	85%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn05-rt.pdf 24AUG2023:17:00

Table 2.7305: Analysis of MPN-SAF Mean Questionnaire Item #5 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Headaches at Week 24 from Baseline			
n	27	23	
Mean (SD)	-0.1 (1.55)	-0.3 (2.40)	
Median	0.0	0.0	
Q1, Q3	0.0, 0.0	-1.0, 0.0	
Min, Max	-4.0, 6.0	-5.0, 6.0	
Difference in Change from Baseline at Week 24			
n [1]	47	27	
n [2]	27	23	
MMRM: Least Squares Mean [SE] (95% CI)	-0.44 [0.34] (-1.11, 0.23)	-0.19 [0.36] (-0.89, 0.52)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.25 [0.49] (-1.23, 0.72)		
MMRM: P-value	0.60		
Corrected Hedges' g (95% CI)	-0.145 (-0.702, 0.412)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.78		
Percent Change in Headaches at Week 24 from Baseline			
n	9	12	
Mean (SD)	-2.4 (125.46)	31.0 (195.78)	
Median	-14.3	-22.2	
Q1, Q3	-100.0, 0.0	-91.7, 50.0	
Min, Max	-100.0, 300.0	-100.0, 600.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7305: Analysis of MPN-SAF Mean Questionnaire Item #5 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	17	14	
n [2]	9	12	
MMRM: Least Squares Mean [SE] (95% CI)	-5.23 [47.61] (-103.28, 92.82)	28.94 [43.26] (-60.15, 118.03)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-34.17 [61.68] (-161.19, 92.85)		
MMRM: P-value	0.58		
Corrected Hedges' g (95% CI)	-0.223 (-1.090, 0.644)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.72		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

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Table 2.7306: Analysis of MPN-SAF Mean Questionnaire Item #6 Score and Change from Baseline

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0106 - Concentration at Baseline		
n	50	29
Mean (SD)	2.9 (2.51)	3.1 (2.74)
Median	3.0	3.0
Q1, Q3	1.0, 4.0	0.0, 5.0
Min, Max	0.0, 9.0	0.0, 8.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
MPN0106 - Concentration at Week 4		
n	60	31
Mean (SD)	2.4 (2.67)	3.3 (2.81)
Median	1.0	3.0
Q1, Q3	0.0, 4.0	1.0, 5.0
Min, Max	0.0, 8.0	0.0, 10.0
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in Concentration at Week 4 from Baseline		
n	45	26
Mean (SD)	-0.4 (2.59)	0.0 (2.76)
Median	0.0	0.0
Q1, Q3	-2.0, 1.0	-2.0, 1.0
Min, Max	-7.0, 5.0	-5.0, 7.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7306: Analysis of MPN-SAF Mean Questionnaire Item #6 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	47	27	
n [2]	45	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.29 [0.36] (-1.01, 0.44)	0.07 [0.45] (-0.83, 0.97)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.36 [0.58] (-1.51, 0.80)		
MMRM: P-value	0.54		
Corrected Hedges' g (95% CI)	-0.149 (-0.632, 0.335)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.93		
Percent Change in Concentration at Week 4 from Baseline			
n	36	19	
Mean (SD)	-7.7 (88.03)	-2.5 (86.40)	
Median	-16.7	0.0	
Q1, Q3	-100.0, 50.0	-60.0, 12.5	
Min, Max	-100.0, 200.0	-100.0, 200.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	37	19	
n [2]	36	19	
MMRM: Least Squares Mean [SE] (95% CI)	-3.83 [14.78] (-33.52, 25.87)	-1.53 [19.34] (-40.38, 37.32)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.30 [24.37] (-51.24, 46.64)		
MMRM: P-value	0.93		
Corrected Hedges' g (95% CI)	-0.026 (-0.582, 0.530)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.23		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.7306: Analysis of MPN-SAF Mean Questionnaire Item #6 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
MPN0106 - Concentration at Week 8			
n	57	27	
Mean (SD)	2.0 (2.22)	2.5 (2.41)	
Median	2.0	3.0	
Q1, Q3	0.0, 3.0	0.0, 4.0	
Min, Max	0.0, 8.0	0.0, 9.0	
Return Rate (%)	86%	69%	
Number of Subjects in Risk	61	36	
Return Rate in Risk (%)	93%	75%	
Change in Concentration at Week 8 from Baseline			
n	44	24	
Mean (SD)	-0.5 (2.30)	-0.5 (2.13)	
Median	0.0	0.0	
Q1, Q3	-1.5, 1.0	-1.5, 0.0	
Min, Max	-7.0, 5.0	-5.0, 5.0	
Difference in Change from Baseline at Week 8			
n [1]	47	27	
n [2]	44	24	
MMRM: Least Squares Mean [SE] (95% CI)	-0.51 [0.30] (-1.10, 0.08)	-0.52 [0.37] (-1.25, 0.21)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.01 [0.47] (-0.93, 0.94)		
MMRM: P-value	0.99		
Corrected Hedges' g (95% CI)	0.003 (-0.494, 0.501)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.89		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7306: Analysis of MPN-SAF Mean Questionnaire Item #6 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in Concentration at Week 8 from Baseline			
n	35	16	
Mean (SD)	-14.3 (69.88)	-15.0 (94.66)	
Median	-14.3	-31.0	
Q1, Q3	-80.0, 50.0	-65.0, 0.0	
Min, Max	-100.0, 166.7	-100.0, 300.0	
Difference in Percent Change from Baseline at Week 8			
n [1]	37	19	
n [2]	35	16	
MMRM: Least Squares Mean [SE] (95% CI)	-12.65 [13.54] (-39.84, 14.54)	-12.66 [18.45] (-49.71, 24.39)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.01 [22.86] (-45.90, 45.91)		
MMRM: P-value	1.00		
Corrected Hedges' g (95% CI)	0.000 (-0.591, 0.592)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.37		
MPN0106 - Concentration at Week 12			
n	51	30	
Mean (SD)	2.0 (2.08)	2.8 (2.70)	
Median	2.0	2.0	
Q1, Q3	0.0, 3.0	0.0, 4.0	
Min, Max	0.0, 7.0	0.0, 10.0	
Return Rate (%)	77%	77%	
Number of Subjects in Risk	59	33	
Return Rate in Risk (%)	86%	91%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7306: Analysis of MPN-SAF Mean Questionnaire Item #6 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Concentration at Week 12 from Baseline			
n	37	26	
Mean (SD)	-0.6 (2.39)	-0.1 (1.58)	
Median	0.0	0.0	
Q1, Q3	-2.0, 1.0	0.0, 1.0	
Min, Max	-7.0, 4.0	-5.0, 2.0	
Difference in Change from Baseline at Week 12			
n [1]	47	27	
n [2]	37	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.63 [0.32] (-1.26, -0.01)	-0.12 [0.36] (-0.83, 0.60)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.52 [0.47] (-1.46, 0.43)		
MMRM: P-value	0.28		
Corrected Hedges' g (95% CI)	-0.273 (-0.777, 0.231)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.24		
Percent Change in Concentration at Week 12 from Baseline			
n	28	18	
Mean (SD)	-18.8 (71.31)	1.0 (61.05)	
Median	-13.4	0.0	
Q1, Q3	-91.7, 0.0	-25.0, 20.0	
Min, Max	-100.0, 133.3	-100.0, 200.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7306: Analysis of MPN-SAF Mean Questionnaire Item #6 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 12			
n [1]	37	19	
n [2]	28	18	
MMRM: Least Squares Mean [SE] (95% CI)	-15.24 [12.81] (-40.98, 10.49)		3.54 [15.92] (-28.42, 35.51)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-18.79 [20.44] (-59.83, 22.26)		
MMRM: P-value	0.36		
Corrected Hedges' g (95% CI)	-0.273 (-0.868, 0.322)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.24		
MPN0106 - Concentration at Week 16			
n	48	30	
Mean (SD)	1.9 (2.16)	2.5 (2.61)	
Median	1.0	2.0	
Q1, Q3	0.0, 3.0	1.0, 3.0	
Min, Max	0.0, 8.0	0.0, 10.0	
Return Rate (%)	73%	77%	
Number of Subjects in Risk	56	33	
Return Rate in Risk (%)	86%	91%	
Change in Concentration at Week 16 from Baseline			
n	36	26	
Mean (SD)	-0.9 (2.10)	-0.2 (2.24)	
Median	-0.5	0.0	
Q1, Q3	-2.0, 0.0	-1.0, 0.0	
Min, Max	-5.0, 4.0	-4.0, 7.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7306: Analysis of MPN-SAF Mean Questionnaire Item #6 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	47	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.80 [0.34] (-1.48, -0.12)	-0.14 [0.39] (-0.92, 0.64)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.66 [0.52] (-1.69, 0.37)		
MMRM: P-value	0.21		
Corrected Hedges' g (95% CI)	-0.322 (-0.830, 0.186)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.20		
Percent Change in Concentration at Week 16 from Baseline			
n	30	18	
Mean (SD)	-23.9 (66.93)	-16.5 (44.91)	
Median	-31.0	-7.1	
Q1, Q3	-83.3, 0.0	-50.0, 0.0	
Min, Max	-100.0, 133.3	-100.0, 100.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	37	19	
n [2]	30	18	
MMRM: Least Squares Mean [SE] (95% CI)	-22.90 [11.84] (-46.69, 0.89)	-15.01 [14.34] (-43.80, 13.78)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-7.89 [18.59] (-45.23, 29.46)		
MMRM: P-value	0.67		
Corrected Hedges' g (95% CI)	-0.122 (-0.707, 0.462)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.32		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7306: Analysis of MPN-SAF Mean Questionnaire Item #6 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0106 - Concentration at Week 20		
n	44	29
Mean (SD)	1.8 (2.18)	3.0 (2.87)
Median	1.0	2.0
Q1, Q3	0.0, 2.5	1.0, 5.0
Min, Max	0.0, 10.0	0.0, 8.0
Return Rate (%)	67%	74%
Number of Subjects in Risk	51	32
Return Rate in Risk (%)	86%	91%
Change in Concentration at Week 20 from Baseline		
n	32	24
Mean (SD)	-0.8 (1.96)	-0.1 (2.57)
Median	-1.0	0.0
Q1, Q3	-2.5, 0.5	-1.0, 0.5
Min, Max	-5.0, 4.0	-5.0, 7.0
Difference in Change from Baseline at Week 20		
n [1]	47	27
n [2]	32	24
MMRM: Least Squares Mean [SE] (95% CI)	-0.62 [0.38] (-1.38, 0.14)	-0.02 [0.42] (-0.86, 0.82)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.60 [0.57] (-1.73, 0.53)	
MMRM: P-value	0.29	
Corrected Hedges' g (95% CI)	-0.279 (-0.811, 0.253)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.27	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7306: Analysis of MPN-SAF Mean Questionnaire Item #6 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in Concentration at Week 20 from Baseline			
n	26	18	
Mean (SD)	-29.1 (61.80)	-11.5 (54.64)	
Median	-25.0	-14.6	
Q1, Q3	-100.0, 0.0	-50.0, 0.0	
Min, Max	-100.0, 100.0	-100.0, 100.0	
Difference in Percent Change from Baseline at Week 20			
n [1]	37	19	
n [2]	26	18	
MMRM: Least Squares Mean [SE] (95% CI)	-28.23 [12.35] (-53.04, -3.42)	-10.93 [14.28] (-39.61, 17.74)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-17.29 [18.89] (-55.23, 20.65)		
MMRM: P-value	0.36		
Corrected Hedges' g (95% CI)	-0.274 (-0.878, 0.330)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.24		
MPN0106 - Concentration at Week 24			
n	41	29	
Mean (SD)	1.9 (1.99)	3.5 (3.08)	
Median	1.0	3.0	
Q1, Q3	0.0, 3.0	1.0, 6.0	
Min, Max	0.0, 7.0	0.0, 10.0	
Return Rate (%)	62%	74%	
Number of Subjects in Risk	48	31	
Return Rate in Risk (%)	85%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7306: Analysis of MPN-SAF Mean Questionnaire Item #6 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Concentration at Week 24 from Baseline			
n	27	23	
Mean (SD)	-0.8 (2.04)	0.2 (2.61)	
Median	-1.0	0.0	
Q1, Q3	-2.0, 0.0	-1.0, 2.0	
Min, Max	-5.0, 3.0	-5.0, 5.0	
Difference in Change from Baseline at Week 24			
n [1]	47	27	
n [2]	27	23	
MMRM: Least Squares Mean [SE] (95% CI)	-0.71 [0.41] (-1.53, 0.10)	0.27 [0.43] (-0.58, 1.13)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.99 [0.59] (-2.16, 0.19)		
MMRM: P-value	0.099		
Corrected Hedges' g (95% CI)	-0.465 (-1.028, 0.099)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.053		
Percent Change in Concentration at Week 24 from Baseline			
n	22	18	
Mean (SD)	-27.0 (62.00)	0.4 (67.14)	
Median	-31.0	0.0	
Q1, Q3	-83.3, 0.0	-50.0, 25.0	
Min, Max	-100.0, 100.0	-100.0, 150.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7306: Analysis of MPN-SAF Mean Questionnaire Item #6 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	37	19	
n [2]	22	18	
MMRM: Least Squares Mean [SE] (95% CI)	-28.29 [14.32] (-57.06, 0.48)	1.76 [15.58] (-29.53, 33.05)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-30.05 [21.18] (-72.59, 12.50)		
MMRM: P-value	0.16		
Corrected Hedges' g (95% CI)	-0.442 (-1.072, 0.189)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.081		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7307: Analysis of MPN-SAF Mean Questionnaire Item #7 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0107 - Dizziness at Baseline		
n	50	29
Mean (SD)	1.6 (2.15)	2.3 (2.95)
Median	0.5	1.0
Q1, Q3	0.0, 3.0	0.0, 5.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
MPN0107 - Dizziness at Week 4		
n	60	31
Mean (SD)	1.8 (2.43)	2.0 (2.68)
Median	1.0	1.0
Q1, Q3	0.0, 3.0	0.0, 3.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in Dizziness at Week 4 from Baseline		
n	45	26
Mean (SD)	0.3 (2.07)	-0.2 (2.71)
Median	0.0	0.0
Q1, Q3	0.0, 1.0	-1.0, 1.0
Min, Max	-5.0, 6.0	-6.0, 4.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7307: Analysis of MPN-SAF Mean Questionnaire Item #7 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	47	27	
n [2]	45	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.34 [0.32] (-0.30, 0.97)	0.13 [0.40] (-0.66, 0.92)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.20 [0.51] (-0.81, 1.22)		
MMRM: P-value	0.69		
Corrected Hedges' g (95% CI)	0.095 (-0.389, 0.578)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.48		
Percent Change in Dizziness at Week 4 from Baseline			
n	22	12	
Mean (SD)	18.4 (97.36)	-14.2 (76.73)	
Median	0.0	-28.3	
Q1, Q3	-37.5, 50.0	-73.3, 50.0	
Min, Max	-100.0, 250.0	-100.0, 100.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	23	13	
n [2]	22	12	
MMRM: Least Squares Mean [SE] (95% CI)	23.03 [21.81] (-21.51, 67.57)	-13.91 [23.16] (-61.21, 33.40)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	36.94 [29.98] (-24.28, 98.17)		
MMRM: P-value	0.23		
Corrected Hedges' g (95% CI)	0.379 (-0.331, 1.088)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.048		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7307: Analysis of MPN-SAF Mean Questionnaire Item #7 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0107 - Dizziness at Week 8		
n	57	27
Mean (SD)	1.5 (1.94)	1.9 (2.28)
Median	1.0	1.0
Q1, Q3	0.0, 2.0	0.0, 3.0
Min, Max	0.0, 8.0	0.0, 9.0
Return Rate (%)	86%	69%
Number of Subjects in Risk	61	36
Return Rate in Risk (%)	93%	75%
Change in Dizziness at Week 8 from Baseline		
n	44	24
Mean (SD)	0.1 (1.85)	-0.3 (2.33)
Median	0.0	0.0
Q1, Q3	-0.5, 1.0	-1.5, 1.0
Min, Max	-5.0, 6.0	-6.0, 3.0
Difference in Change from Baseline at Week 8		
n [1]	47	27
n [2]	44	24
MMRM: Least Squares Mean [SE] (95% CI)	0.13 [0.27] (-0.41, 0.67)	0.00 [0.33] (-0.66, 0.66)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.13 [0.42] (-0.72, 0.98)	
MMRM: P-value	0.76	
Corrected Hedges' g (95% CI)	0.074 (-0.423, 0.572)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.69	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7307: Analysis of MPN-SAF Mean Questionnaire Item #7 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in Dizziness at Week 8 from Baseline			
n	21	10	
Mean (SD)	12.1 (118.52)	-16.1 (88.28)	
Median	-25.0	-38.9	
Q1, Q3	-50.0, 25.0	-66.7, 20.0	
Min, Max	-100.0, 300.0	-100.0, 200.0	
Difference in Percent Change from Baseline at Week 8			
n [1]	23	13	
n [2]	21	10	
MMRM: Least Squares Mean [SE] (95% CI)	12.70 [25.18] (-38.72, 64.12)	9.81 [29.33] (-50.09, 69.72)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	2.89 [37.10] (-72.87, 78.65)		
MMRM: P-value	0.94		
Corrected Hedges' g (95% CI)	0.026 (-0.727, 0.779)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.30		
MPN0107 - Dizziness at Week 12			
n	51	30	
Mean (SD)	1.4 (2.03)	1.9 (2.52)	
Median	0.0	1.0	
Q1, Q3	0.0, 2.0	0.0, 2.0	
Min, Max	0.0, 9.0	0.0, 10.0	
Return Rate (%)	77%	77%	
Number of Subjects in Risk	59	33	
Return Rate in Risk (%)	86%	91%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7307: Analysis of MPN-SAF Mean Questionnaire Item #7 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Dizziness at Week 12 from Baseline			
n	37	26	
Mean (SD)	0.1 (1.93)	-0.3 (2.19)	
Median	0.0	0.0	
Q1, Q3	-1.0, 0.0	-1.0, 1.0	
Min, Max	-3.0, 7.0	-6.0, 2.0	
Difference in Change from Baseline at Week 12			
n [1]	47	27	
n [2]	37	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.20 [0.31] (-0.42, 0.81)	-0.13 [0.34] (-0.81, 0.56)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.32 [0.46] (-0.59, 1.24)		
MMRM: P-value	0.48		
Corrected Hedges' g (95% CI)	0.175 (-0.327, 0.678)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.47		
Percent Change in Dizziness at Week 12 from Baseline			
n	18	12	
Mean (SD)	8.8 (122.95)	-26.9 (65.02)	
Median	-25.0	-33.3	
Q1, Q3	-66.7, 33.3	-91.7, 0.0	
Min, Max	-100.0, 350.0	-100.0, 100.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7307: Analysis of MPN-SAF Mean Questionnaire Item #7 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 12			
n [1]	23	13	
n [2]	18	12	
MMRM: Least Squares Mean [SE] (95% CI)	32.35 [28.75] (-26.37, 91.06)	-17.54 [32.08] (-83.05, 47.97)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	49.89 [41.65] (-35.16, 134.95)		
MMRM: P-value	0.24		
Corrected Hedges' g (95% CI)	0.412 (-0.326, 1.150)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.16		
MPN0107 - Dizziness at Week 16			
n	48	30	
Mean (SD)	1.4 (1.99)	1.8 (2.73)	
Median	0.0	0.5	
Q1, Q3	0.0, 2.0	0.0, 2.0	
Min, Max	0.0, 8.0	0.0, 10.0	
Return Rate (%)	73%	77%	
Number of Subjects in Risk	56	33	
Return Rate in Risk (%)	86%	91%	
Change in Dizziness at Week 16 from Baseline			
n	36	26	
Mean (SD)	-0.1 (1.88)	0.0 (2.65)	
Median	0.0	0.0	
Q1, Q3	-0.5, 0.0	-1.0, 1.0	
Min, Max	-5.0, 4.0	-6.0, 6.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7307: Analysis of MPN-SAF Mean Questionnaire Item #7 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	47	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.06 [0.33] (-0.60, 0.71)		0.22 [0.37] (-0.53, 0.96)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.16 [0.49] (-1.15, 0.83)		
MMRM: P-value	0.75		
Corrected Hedges' g (95% CI)	-0.081 (-0.586, 0.423)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.83		
Percent Change in Dizziness at Week 16 from Baseline			
n	17	12	
Mean (SD)	11.1 (135.80)	-3.7 (94.62)	
Median	-20.0	-22.2	
Q1, Q3	-100.0, 0.0	-63.3, 0.0	
Min, Max	-100.0, 400.0	-100.0, 200.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	23	13	
n [2]	17	12	
MMRM: Least Squares Mean [SE] (95% CI)	14.52 [29.55] (-45.82, 74.86)		4.66 [33.61] (-63.98, 73.30)
MMRM: Least Squares Mean Difference [SE] (95% CI)	9.86 [43.42] (-78.82, 98.54)		
MMRM: P-value	0.82		
Corrected Hedges' g (95% CI)	0.080 (-0.659, 0.819)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.26		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7307: Analysis of MPN-SAF Mean Questionnaire Item #7 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0107 - Dizziness at Week 20		
n	44	29
Mean (SD)	1.1 (1.69)	2.4 (2.89)
Median	0.0	1.0
Q1, Q3	0.0, 2.0	0.0, 4.0
Min, Max	0.0, 7.0	0.0, 10.0
Return Rate (%)	67%	74%
Number of Subjects in Risk	51	32
Return Rate in Risk (%)	86%	91%
Change in Dizziness at Week 20 from Baseline		
n	32	24
Mean (SD)	-0.5 (1.95)	0.3 (2.74)
Median	0.0	0.5
Q1, Q3	-1.0, 0.0	-0.5, 2.0
Min, Max	-5.0, 4.0	-6.0, 5.0
Difference in Change from Baseline at Week 20		
n [1]	47	27
n [2]	32	24
MMRM: Least Squares Mean [SE] (95% CI)	-0.32 [0.33] (-0.98, 0.33)	0.57 [0.38] (-0.18, 1.32)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.90 [0.50] (-1.89, 0.10)	
MMRM: P-value	0.076	
Corrected Hedges' g (95% CI)	-0.477 (-1.013, 0.060)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.10	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7307: Analysis of MPN-SAF Mean Questionnaire Item #7 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Dizziness at Week 20 from Baseline		
n	14	12
Mean (SD)	-35.1 (104.83)	8.6 (122.19)
Median	-83.3	-16.7
Q1, Q3	-100.0, -20.0	-75.0, 10.0
Min, Max	-100.0, 200.0	-100.0, 300.0
Difference in Percent Change from Baseline at Week 20		
n [1]	23	13
n [2]	14	12
MMRM: Least Squares Mean [SE] (95% CI)	-22.19 [27.91] (-79.20, 34.82)	18.33 [31.48] (-45.97, 82.63)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-40.52 [40.62] (-123.48, 42.45)	
MMRM: P-value	0.33	
Corrected Hedges' g (95% CI)	-0.368 (-1.146, 0.409)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.44	
MPN0107 - Dizziness at Week 24		
n	41	29
Mean (SD)	1.1 (1.88)	2.1 (2.92)
Median	0.0	1.0
Q1, Q3	0.0, 2.0	0.0, 3.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	62%	74%
Number of Subjects in Risk	48	31
Return Rate in Risk (%)	85%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn07-rt.pdf 24AUG2023:17:00

Table 2.7307: Analysis of MPN-SAF Mean Questionnaire Item #7 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Dizziness at Week 24 from Baseline			
n	27	23	
Mean (SD)	0.0 (2.43)	-0.2 (2.37)	
Median	0.0	0.0	
Q1, Q3	-1.0, 0.0	-1.0, 1.0	
Min, Max	-5.0, 9.0	-5.0, 4.0	
Difference in Change from Baseline at Week 24			
n [1]	47	27	
n [2]	27	23	
MMRM: Least Squares Mean [SE] (95% CI)		-0.09 [0.39] (-0.86, 0.69)	0.06 [0.44] (-0.81, 0.93)
MMRM: Least Squares Mean Difference [SE] (95% CI)		-0.14 [0.58] (-1.31, 1.02)	
MMRM: P-value	0.81		
Corrected Hedges' g (95% CI)	-0.069 (-0.625, 0.488)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.80		
Percent Change in Dizziness at Week 24 from Baseline			
n	11	12	
Mean (SD)	-20.1 (100.29)	-4.5 (90.11)	
Median	-37.5	-5.6	
Q1, Q3	-100.0, 50.0	-75.0, 33.3	
Min, Max	-100.0, 200.0	-100.0, 200.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7307: Analysis of MPN-SAF Mean Questionnaire Item #7 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	23	13	
n [2]	11	12	
MMRM: Least Squares Mean [SE] (95% CI)	-10.12 [25.67] (-62.54, 42.30)	5.14 [26.19] (-48.36, 58.63)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-15.26 [34.98] (-86.70, 56.19)		
MMRM: P-value	0.67		
Corrected Hedges' g (95% CI)	-0.167 (-0.986, 0.653)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.88		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7308: Analysis of MPN-SAF Mean Questionnaire Item #8 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0108 - Numbness at Baseline		
n	50	29
Mean (SD)	1.5 (2.08)	1.8 (2.07)
Median	0.0	2.0
Q1, Q3	0.0, 3.0	0.0, 3.0
Min, Max	0.0, 8.0	0.0, 6.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
MPN0108 - Numbness at Week 4		
n	60	31
Mean (SD)	1.4 (1.90)	2.3 (2.58)
Median	0.0	2.0
Q1, Q3	0.0, 2.5	0.0, 3.0
Min, Max	0.0, 7.0	0.0, 10.0
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in Numbness at Week 4 from Baseline		
n	45	26
Mean (SD)	0.2 (1.88)	0.8 (2.57)
Median	0.0	0.0
Q1, Q3	0.0, 1.0	-1.0, 2.0
Min, Max	-3.0, 7.0	-3.0, 7.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn08-rt.pdf 24AUG2023:17:00

Table 2.7308: Analysis of MPN-SAF Mean Questionnaire Item #8 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	47	27	
n [2]	45	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.01 [0.31] (-0.63, 0.62)	0.85 [0.38] (0.09, 1.61)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.86 [0.49] (-1.84, 0.12)		
MMRM: P-value	0.086		
Corrected Hedges' g (95% CI)	-0.415 (-0.902, 0.073)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.76		
Percent Change in Numbness at Week 4 from Baseline			
n	21	13	
Mean (SD)	1.6 (117.87)	-20.9 (37.33)	
Median	0.0	-25.0	
Q1, Q3	-100.0, 33.3	-50.0, 0.0	
Min, Max	-100.0, 400.0	-66.7, 66.7	
Difference in Percent Change from Baseline at Week 4			
n [1]	22	13	
n [2]	21	13	
MMRM: Least Squares Mean [SE] (95% CI)	-8.62 [24.85] (-59.43, 42.19)	-25.05 [28.18] (-82.68, 32.57)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	16.43 [38.08] (-61.45, 94.31)		
MMRM: P-value	0.67		
Corrected Hedges' g (95% CI)	0.147 (-0.546, 0.839)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.15		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7308: Analysis of MPN-SAF Mean Questionnaire Item #8 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0108 - Numbness at Week 8		
n	57	27
Mean (SD)	1.4 (1.74)	1.6 (2.24)
Median	0.0	1.0
Q1, Q3	0.0, 3.0	0.0, 2.0
Min, Max	0.0, 6.0	0.0, 9.0
Return Rate (%)	86%	69%
Number of Subjects in Risk	61	36
Return Rate in Risk (%)	93%	75%
Change in Numbness at Week 8 from Baseline		
n	44	24
Mean (SD)	0.0 (1.67)	-0.1 (1.77)
Median	0.0	0.0
Q1, Q3	-1.0, 1.0	-1.5, 0.5
Min, Max	-3.0, 5.0	-3.0, 4.0
Difference in Change from Baseline at Week 8		
n [1]	47	27
n [2]	44	24
MMRM: Least Squares Mean [SE] (95% CI)	-0.07 [0.26] (-0.58, 0.44)	-0.03 [0.30] (-0.64, 0.58)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.04 [0.39] (-0.83, 0.74)	
MMRM: P-value	0.91	
Corrected Hedges' g (95% CI)	-0.027 (-0.524, 0.471)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.92	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn08-rt.pdf 24AUG2023:17:00

Table 2.7308: Analysis of MPN-SAF Mean Questionnaire Item #8 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in Numbness at Week 8 from Baseline			
n	20	11	
Mean (SD)	-3.5 (98.92)	-42.4 (43.92)	
Median	-31.0	-50.0	
Q1, Q3	-66.7, 25.0	-60.0, -33.3	
Min, Max	-100.0, 200.0	-100.0, 50.0	
Difference in Percent Change from Baseline at Week 8			
n [1]	22	13	
n [2]	20	11	
MMRM: Least Squares Mean [SE] (95% CI)		5.58 [26.56] (-48.75, 59.91)	-48.35 [31.14] (-112.05, 15.35)
MMRM: Least Squares Mean Difference [SE] (95% CI)		53.93 [41.36] (-30.67, 138.53)	
MMRM: P-value		0.20	
Corrected Hedges' g (95% CI)		0.462 (-0.283, 1.207)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value		0.51	
MPN0108 - Numbness at Week 12			
n	51	30	
Mean (SD)	1.7 (1.95)	1.6 (2.37)	
Median	1.0	1.0	
Q1, Q3	0.0, 3.0	0.0, 2.0	
Min, Max	0.0, 7.0	0.0, 10.0	
Return Rate (%)	77%	77%	
Number of Subjects in Risk	59	33	
Return Rate in Risk (%)	86%	91%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7308: Analysis of MPN-SAF Mean Questionnaire Item #8 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Numbness at Week 12 from Baseline			
n	37	26	
Mean (SD)	0.7 (1.75)	-0.1 (2.07)	
Median	0.0	0.0	
Q1, Q3	0.0, 2.0	-1.0, 0.0	
Min, Max	-3.0, 5.0	-5.0, 4.0	
Difference in Change from Baseline at Week 12			
n [1]	47	27	
n [2]	37	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.39 [0.30] (-0.20, 0.98)	-0.08 [0.34] (-0.76, 0.60)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.47 [0.45] (-0.43, 1.36)		
MMRM: P-value	0.30		
Corrected Hedges' g (95% CI)	0.260 (-0.244, 0.764)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.27		
Percent Change in Numbness at Week 12 from Baseline			
n	17	12	
Mean (SD)	38.7 (127.10)	-31.4 (62.94)	
Median	0.0	-50.0	
Q1, Q3	-50.0, 50.0	-75.0, 0.0	
Min, Max	-100.0, 400.0	-100.0, 100.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7308: Analysis of MPN-SAF Mean Questionnaire Item #8 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 12		
n [1]	22	13
n [2]	17	12
MMRM: Least Squares Mean [SE] (95% CI)	30.13 [28.49] (-28.13, 88.40)	-36.22 [33.24] (-104.21, 31.76)
MMRM: Least Squares Mean Difference [SE] (95% CI)	66.36 [44.19] (-24.02, 156.74)	
MMRM: P-value	0.14	
Corrected Hedges' g (95% CI)	0.553 (-0.199, 1.306)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.40	
MPN0108 - Numbness at Week 16		
n	48	30
Mean (SD)	1.8 (2.23)	2.0 (2.35)
Median	1.0	2.0
Q1, Q3	0.0, 3.5	0.0, 3.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	73%	77%
Number of Subjects in Risk	56	33
Return Rate in Risk (%)	86%	91%
Change in Numbness at Week 16 from Baseline		
n	36	26
Mean (SD)	0.4 (2.03)	0.5 (2.18)
Median	0.0	0.0
Q1, Q3	0.0, 1.5	-1.0, 2.0
Min, Max	-5.0, 5.0	-4.0, 5.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7308: Analysis of MPN-SAF Mean Questionnaire Item #8 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	47	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.24 [0.33] (-0.41, 0.90)	0.58 [0.37] (-0.16, 1.33)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.34 [0.49] (-1.32, 0.65)		
MMRM: P-value	0.50		
Corrected Hedges' g (95% CI)	-0.171 (-0.677, 0.334)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.49		
Percent Change in Numbness at Week 16 from Baseline			
n	16	12	
Mean (SD)	44.5 (142.52)	9.7 (95.50)	
Median	0.0	-25.0	
Q1, Q3	-60.7, 112.5	-50.0, 58.3	
Min, Max	-100.0, 300.0	-100.0, 250.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	22	13	
n [2]	16	12	
MMRM: Least Squares Mean [SE] (95% CI)	33.19 [31.82] (-31.89, 98.28)	4.71 [36.61] (-70.16, 79.58)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	28.48 [48.89] (-71.50, 128.47)		
MMRM: P-value	0.56		
Corrected Hedges' g (95% CI)	0.218 (-0.533, 0.968)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.67		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7308: Analysis of MPN-SAF Mean Questionnaire Item #8 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0108 - Numbness at Week 20		
n	44	29
Mean (SD)	1.7 (2.29)	2.3 (2.74)
Median	0.0	1.0
Q1, Q3	0.0, 3.0	0.0, 4.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	67%	74%
Number of Subjects in Risk	51	32
Return Rate in Risk (%)	86%	91%
Change in Numbness at Week 20 from Baseline		
n	32	24
Mean (SD)	0.7 (2.29)	0.6 (1.77)
Median	0.0	0.0
Q1, Q3	0.0, 2.0	0.0, 2.0
Min, Max	-7.0, 5.0	-3.0, 4.0
Difference in Change from Baseline at Week 20		
n [1]	47	27
n [2]	32	24
MMRM: Least Squares Mean [SE] (95% CI)	0.42 [0.36] (-0.28, 1.13)	0.53 [0.40] (-0.28, 1.33)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.10 [0.53] (-1.17, 0.97)	
MMRM: P-value	0.85	
Corrected Hedges' g (95% CI)	-0.050 (-0.579, 0.479)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.87	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7308: Analysis of MPN-SAF Mean Questionnaire Item #8 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Numbness at Week 20 from Baseline		
n	14	11
Mean (SD)	35.7 (141.66)	20.2 (81.07)
Median	0.0	33.3
Q1, Q3	-100.0, 125.0	-50.0, 100.0
Min, Max	-100.0, 300.0	-100.0, 150.0
Difference in Percent Change from Baseline at Week 20		
n [1]	22	13
n [2]	14	11
MMRM: Least Squares Mean [SE] (95% CI)	27.60 [31.34] (-36.50, 91.69)	6.05 [35.03] (-65.60, 77.70)
MMRM: Least Squares Mean Difference [SE] (95% CI)	21.54 [47.46] (-75.53, 118.62)	
MMRM: P-value	0.65	
Corrected Hedges' g (95% CI)	0.178 (-0.613, 0.970)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.41	
MPN0108 - Numbness at Week 24		
n	41	29
Mean (SD)	1.6 (2.11)	1.9 (2.68)
Median	1.0	1.0
Q1, Q3	0.0, 3.0	0.0, 4.0
Min, Max	0.0, 8.0	0.0, 10.0
Return Rate (%)	62%	74%
Number of Subjects in Risk	48	31
Return Rate in Risk (%)	85%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7308: Analysis of MPN-SAF Mean Questionnaire Item #8 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Numbness at Week 24 from Baseline			
n	27	23	
Mean (SD)	0.8 (1.80)	0.1 (2.35)	
Median	0.0	0.0	
Q1, Q3	0.0, 2.0	-1.0, 1.0	
Min, Max	-3.0, 4.0	-6.0, 5.0	
Difference in Change from Baseline at Week 24			
n [1]	47	27	
n [2]	27	23	
MMRM: Least Squares Mean [SE] (95% CI)	0.50 [0.38] (-0.25, 1.26)	0.02 [0.41] (-0.80, 0.85)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.48 [0.56] (-0.63, 1.59)		
MMRM: P-value	0.39		
Corrected Hedges' g (95% CI)	0.239 (-0.319, 0.797)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.48		
Percent Change in Numbness at Week 24 from Baseline			
n	11	11	
Mean (SD)	59.1 (159.40)	-20.8 (65.54)	
Median	0.0	-33.3	
Q1, Q3	-50.0, 100.0	-75.0, 33.3	
Min, Max	-100.0, 400.0	-100.0, 100.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7308: Analysis of MPN-SAF Mean Questionnaire Item #8 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	22	13	
n [2]	11	11	
MMRM: Least Squares Mean [SE] (95% CI)	47.27 [33.87] (-22.01, 116.54)	-31.50 [37.93] (-109.07, 46.07)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	78.77 [50.92] (-25.37, 182.90)		
MMRM: P-value	0.13		
Corrected Hedges' g (95% CI)	0.635 (-0.221, 1.492)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.59		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.7309: Analysis of MPN-SAF Mean Questionnaire Item #9 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0109 - Difficulty Sleep at Baseline		
n	50	29
Mean (SD)	3.5 (3.36)	3.3 (3.04)
Median	3.0	3.0
Q1, Q3	0.0, 7.0	0.0, 5.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
MPN0109 - Difficulty Sleep at Week 4		
n	60	31
Mean (SD)	2.4 (2.78)	3.2 (3.27)
Median	1.0	2.0
Q1, Q3	0.0, 4.5	1.0, 7.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in Difficulty Sleep at Week 4 from Baseline		
n	45	26
Mean (SD)	-0.4 (2.92)	0.0 (2.15)
Median	0.0	0.0
Q1, Q3	-2.0, 0.0	-1.0, 1.0
Min, Max	-9.0, 9.0	-6.0, 4.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn09-rt.pdf 24AUG2023:17:00

Table 2.7309: Analysis of MPN-SAF Mean Questionnaire Item #9 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	47	27	
n [2]	45	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.40 [0.41] (-1.22, 0.42)	0.37 [0.50] (-0.62, 1.37)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.77 [0.64] (-2.06, 0.51)		
MMRM: P-value	0.23		
Corrected Hedges' g (95% CI)	-0.287 (-0.772, 0.198)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.39		
Percent Change in Difficulty Sleep at Week 4 from Baseline			
n	31	19	
Mean (SD)	-10.8 (95.87)	1.7 (75.15)	
Median	-25.0	0.0	
Q1, Q3	-66.7, 0.0	-60.0, 14.3	
Min, Max	-100.0, 400.0	-100.0, 200.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	32	19	
n [2]	31	19	
MMRM: Least Squares Mean [SE] (95% CI)	-21.21 [16.23] (-53.91, 11.48)	0.05 [20.33] (-40.90, 41.01)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-21.27 [25.94] (-73.51, 30.98)		
MMRM: P-value	0.42		
Corrected Hedges' g (95% CI)	-0.233 (-0.806, 0.340)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.23		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7309: Analysis of MPN-SAF Mean Questionnaire Item #9 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0109 - Difficulty Sleep at Week 8		
n	57	27
Mean (SD)	2.0 (2.24)	2.5 (2.69)
Median	1.0	2.0
Q1, Q3	0.0, 4.0	0.0, 4.0
Min, Max	0.0, 8.0	0.0, 10.0
Return Rate (%)	86%	69%
Number of Subjects in Risk	61	36
Return Rate in Risk (%)	93%	75%
Change in Difficulty Sleep at Week 8 from Baseline		
n	44	24
Mean (SD)	-0.8 (3.02)	-0.8 (2.86)
Median	0.0	0.0
Q1, Q3	-3.0, 0.5	-2.0, 1.0
Min, Max	-10.0, 8.0	-7.0, 4.0
Difference in Change from Baseline at Week 8		
n [1]	47	27
n [2]	44	24
MMRM: Least Squares Mean [SE] (95% CI)	-0.75 [0.37] (-1.49, -0.02)	-0.71 [0.45] (-1.60, 0.18)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.04 [0.57] (-1.19, 1.10)	
MMRM: P-value	0.94	
Corrected Hedges' g (95% CI)	-0.018 (-0.515, 0.479)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.50	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7309: Analysis of MPN-SAF Mean Questionnaire Item #9 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Difficulty Sleep at Week 8 from Baseline		
n	30	16
Mean (SD)	-12.2 (93.57)	-8.0 (105.21)
Median	-37.5	-36.7
Q1, Q3	-66.7, 0.0	-85.0, 22.2
Min, Max	-100.0, 300.0	-100.0, 300.0
Difference in Percent Change from Baseline at Week 8		
n [1]	32	19
n [2]	30	16
MMRM: Least Squares Mean [SE] (95% CI)	-26.99 [18.02] (-63.28, 9.31)	-10.33 [23.29] (-57.24, 36.59)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-16.66 [29.44] (-75.95, 42.63)	
MMRM: P-value	0.57	
Corrected Hedges' g (95% CI)	-0.169 (-0.777, 0.439)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.79	
MPN0109 - Difficulty Sleep at Week 12		
n	51	30
Mean (SD)	1.5 (2.01)	2.8 (2.98)
Median	1.0	2.0
Q1, Q3	0.0, 3.0	0.0, 3.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	77%	77%
Number of Subjects in Risk	59	33
Return Rate in Risk (%)	86%	91%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7309: Analysis of MPN-SAF Mean Questionnaire Item #9 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Difficulty Sleep at Week 12 from Baseline		
n	37	26
Mean (SD)	-1.1 (2.37)	-0.8 (2.80)
Median	0.0	-0.5
Q1, Q3	-2.0, 0.0	-2.0, 0.0
Min, Max	-9.0, 3.0	-6.0, 7.0
Difference in Change from Baseline at Week 12		
n [1]	47	27
n [2]	37	26
MMRM: Least Squares Mean [SE] (95% CI)	-1.24 [0.38] (-1.99, -0.49)	-0.60 [0.42] (-1.44, 0.24)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.64 [0.56] (-1.75, 0.47)	
MMRM: P-value	0.26	
Corrected Hedges' g (95% CI)	-0.284 (-0.788, 0.220)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.76	
Percent Change in Difficulty Sleep at Week 12 from Baseline		
n	26	18
Mean (SD)	-37.5 (54.72)	-37.3 (43.04)
Median	-50.0	-36.7
Q1, Q3	-100.0, 0.0	-60.0, 0.0
Min, Max	-100.0, 75.0	-100.0, 50.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7309: Analysis of MPN-SAF Mean Questionnaire Item #9 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 12		
n [1]	32	19
n [2]	26	18
MMRM: Least Squares Mean [SE] (95% CI)	-49.19 [10.67] (-70.68, -27.70)	-38.10 [11.97] (-62.20, -14.00)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-11.09 [15.87] (-43.04, 20.87)	
MMRM: P-value	0.49	
Corrected Hedges' g (95% CI)	-0.206 (-0.808, 0.397)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.26	
MPN0109 - Difficulty Sleep at Week 16		
n	48	30
Mean (SD)	2.0 (2.96)	3.2 (2.73)
Median	1.0	3.0
Q1, Q3	0.0, 2.5	0.0, 5.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	73%	77%
Number of Subjects in Risk	56	33
Return Rate in Risk (%)	86%	91%
Change in Difficulty Sleep at Week 16 from Baseline		
n	36	26
Mean (SD)	-0.4 (3.47)	-0.1 (3.29)
Median	0.0	0.0
Q1, Q3	-2.0, 1.0	-1.0, 1.0
Min, Max	-10.0, 8.0	-7.0, 8.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7309: Analysis of MPN-SAF Mean Questionnaire Item #9 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	47	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.38 [0.48] (-1.33, 0.57)	0.16 [0.56] (-0.95, 1.27)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.54 [0.73] (-1.99, 0.91)		
MMRM: P-value	0.46		
Corrected Hedges' g (95% CI)	-0.188 (-0.693, 0.318)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.48		
Percent Change in Difficulty Sleep at Week 16 from Baseline			
n	24	18	
Mean (SD)	15.7 (192.11)	-3.2 (60.95)	
Median	-41.4	-10.0	
Q1, Q3	-100.0, 37.5	-50.0, 50.0	
Min, Max	-100.0, 800.0	-100.0, 100.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	32	19	
n [2]	24	18	
MMRM: Least Squares Mean [SE] (95% CI)	-12.14 [27.75] (-68.04, 43.76)	0.46 [33.91] (-67.83, 68.75)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-12.60 [43.77] (-100.76, 75.56)		
MMRM: P-value	0.77		
Corrected Hedges' g (95% CI)	-0.089 (-0.700, 0.523)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.17		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7309: Analysis of MPN-SAF Mean Questionnaire Item #9 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
MPN0109 - Difficulty Sleep at Week 20			
n	44	29	
Mean (SD)	1.6 (2.14)	3.3 (2.98)	
Median	0.0	2.0	
Q1, Q3	0.0, 3.0	1.0, 5.0	
Min, Max	0.0, 8.0	0.0, 10.0	
Return Rate (%)	67%	74%	
Number of Subjects in Risk	51	32	
Return Rate in Risk (%)	86%	91%	
Change in Difficulty Sleep at Week 20 from Baseline			
n	32	24	
Mean (SD)	-1.0 (2.87)	-0.1 (2.72)	
Median	0.0	0.5	
Q1, Q3	-2.0, 0.0	-2.5, 1.0	
Min, Max	-10.0, 5.0	-6.0, 5.0	
Difference in Change from Baseline at Week 20			
n [1]	47	27	
n [2]	32	24	
MMRM: Least Squares Mean [SE] (95% CI)	-0.83 [0.42] (-1.66, 0.01)	-0.05 [0.47] (-1.00, 0.90)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.78 [0.63] (-2.04, 0.47)		
MMRM: P-value	0.22		
Corrected Hedges' g (95% CI)	-0.328 (-0.860, 0.205)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.19		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7309: Analysis of MPN-SAF Mean Questionnaire Item #9 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Difficulty Sleep at Week 20 from Baseline		
n	20	17
Mean (SD)	-9.3 (140.60)	-9.6 (78.34)
Median	-45.0	-20.0
Q1, Q3	-100.0, 0.0	-60.0, 25.0
Min, Max	-100.0, 500.0	-100.0, 166.7
Difference in Percent Change from Baseline at Week 20		
n [1]	32	19
n [2]	20	17
MMRM: Least Squares Mean [SE] (95% CI)	-30.63 [22.08] (-75.11, 13.85)	-10.70 [25.91] (-62.88, 41.49)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-19.93 [34.00] (-88.41, 48.54)	
MMRM: P-value	0.56	
Corrected Hedges' g (95% CI)	-0.190 (-0.838, 0.458)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.11	
MPN0109 - Difficulty Sleep at Week 24		
n	41	29
Mean (SD)	1.7 (1.99)	3.6 (3.34)
Median	1.0	2.0
Q1, Q3	0.0, 3.0	1.0, 5.0
Min, Max	0.0, 7.0	0.0, 10.0
Return Rate (%)	62%	74%
Number of Subjects in Risk	48	31
Return Rate in Risk (%)	85%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7309: Analysis of MPN-SAF Mean Questionnaire Item #9 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Difficulty Sleep at Week 24 from Baseline			
n	27	23	
Mean (SD)	-0.8 (2.69)	0.2 (2.73)	
Median	0.0	0.0	
Q1, Q3	-2.0, 1.0	-1.0, 1.0	
Min, Max	-9.0, 3.0	-7.0, 8.0	
Difference in Change from Baseline at Week 24			
n [1]	47	27	
n [2]	27	23	
MMRM: Least Squares Mean [SE] (95% CI)	-0.80 [0.43] (-1.67, 0.06)	0.48 [0.47] (-0.47, 1.42)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.28 [0.64] (-2.55, -0.01)		
MMRM: P-value	0.049		
Corrected Hedges' g (95% CI)	-0.557 (-1.124, 0.010)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.19		
Percent Change in Difficulty Sleep at Week 24 from Baseline			
n	16	17	
Mean (SD)	-21.4 (101.30)	7.1 (63.63)	
Median	-37.5	0.0	
Q1, Q3	-95.0, 0.0	-33.3, 25.0	
Min, Max	-100.0, 300.0	-100.0, 166.7	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7309: Analysis of MPN-SAF Mean Questionnaire Item #9 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	32	19	
n [2]	16	17	
MMRM: Least Squares Mean [SE] (95% CI)	-42.38 [17.42] (-77.47, -7.28)	5.40 [18.72] (-32.31, 43.11)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-47.77 [25.51] (-99.15, 3.60)		
MMRM: P-value	0.068		
Corrected Hedges' g (95% CI)	-0.633 (-1.332, 0.067)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.022		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

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Table 2.7310: Analysis of MPN-SAF Mean Questionnaire Item #10 Score and Change from Baseline

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0110 - Depression at Baseline		
n	50	29
Mean (SD)	2.7 (2.69)	2.5 (3.08)
Median	2.0	1.0
Q1, Q3	0.0, 5.0	0.0, 5.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
MPN0110 - Depression at Week 4		
n	60	31
Mean (SD)	2.0 (2.47)	2.3 (2.60)
Median	1.0	2.0
Q1, Q3	0.0, 3.0	0.0, 4.0
Min, Max	0.0, 8.0	0.0, 10.0
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in Depression at Week 4 from Baseline		
n	45	26
Mean (SD)	-0.2 (1.87)	-0.6 (2.66)
Median	0.0	0.0
Q1, Q3	-1.0, 1.0	-1.0, 0.0
Min, Max	-6.0, 4.0	-6.0, 4.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7310: Analysis of MPN-SAF Mean Questionnaire Item #10 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	47	27	
n [2]	45	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.20 [0.31] (-0.81, 0.41)	-0.52 [0.37] (-1.27, 0.22)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.32 [0.48] (-0.64, 1.28)		
MMRM: P-value	0.50		
Corrected Hedges' g (95% CI)	0.160 (-0.324, 0.644)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.50		
Percent Change in Depression at Week 4 from Baseline			
n	31	15	
Mean (SD)	-5.9 (94.60)	-45.6 (46.20)	
Median	0.0	-40.0	
Q1, Q3	-85.7, 33.3	-100.0, -20.0	
Min, Max	-100.0, 400.0	-100.0, 60.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	32	15	
n [2]	31	15	
MMRM: Least Squares Mean [SE] (95% CI)	-3.16 [15.48] (-34.42, 28.09)	-49.71 [21.30] (-92.74, -6.69)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	46.55 [26.41] (-6.79, 99.88)		
MMRM: P-value	0.085		
Corrected Hedges' g (95% CI)	0.538 (-0.088, 1.164)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.041		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7310: Analysis of MPN-SAF Mean Questionnaire Item #10 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
MPN0110 - Depression at Week 8			
n	57	27	
Mean (SD)	2.1 (2.71)	1.7 (2.16)	
Median	1.0	1.0	
Q1, Q3	0.0, 4.0	0.0, 2.0	
Min, Max	0.0, 9.0	0.0, 10.0	
Return Rate (%)	86%	69%	
Number of Subjects in Risk	61	36	
Return Rate in Risk (%)	93%	75%	
Change in Depression at Week 8 from Baseline			
n	44	24	
Mean (SD)	0.0 (2.25)	-0.9 (2.36)	
Median	0.0	0.0	
Q1, Q3	-1.0, 0.0	-2.0, 0.0	
Min, Max	-6.0, 8.0	-8.0, 3.0	
Difference in Change from Baseline at Week 8			
n [1]	47	27	
n [2]	44	24	
MMRM: Least Squares Mean [SE] (95% CI)	-0.02 [0.34] (-0.69, 0.65)	-0.76 [0.42] (-1.60, 0.08)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.74 [0.54] (-0.33, 1.81)		
MMRM: P-value	0.17		
Corrected Hedges' g (95% CI)	0.336 (-0.165, 0.837)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.48		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7310: Analysis of MPN-SAF Mean Questionnaire Item #10 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in Depression at Week 8 from Baseline			
n	30	13	
Mean (SD)	10.1 (164.55)	-55.5 (37.05)	
Median	-17.1	-50.0	
Q1, Q3	-50.0, 0.0	-100.0, -33.3	
Min, Max	-100.0, 800.0	-100.0, 0.0	
Difference in Percent Change from Baseline at Week 8			
n [1]	32	15	
n [2]	30	13	
MMRM: Least Squares Mean [SE] (95% CI)	4.81 [25.70] (-47.09, 56.71)	-52.48 [37.28] (-127.77, 22.80)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	57.29 [45.29] (-34.16, 148.75)		
MMRM: P-value	0.21		
Corrected Hedges' g (95% CI)	0.405 (-0.252, 1.061)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.012		
MPN0110 - Depression at Week 12			
n	51	30	
Mean (SD)	1.8 (2.35)	1.9 (2.73)	
Median	1.0	1.0	
Q1, Q3	0.0, 3.0	0.0, 2.0	
Min, Max	0.0, 8.0	0.0, 10.0	
Return Rate (%)	77%	77%	
Number of Subjects in Risk	59	33	
Return Rate in Risk (%)	86%	91%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7310: Analysis of MPN-SAF Mean Questionnaire Item #10 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Depression at Week 12 from Baseline			
n	37	26	
Mean (SD)	0.1 (2.27)	-0.5 (2.42)	
Median	0.0	0.0	
Q1, Q3	-1.0, 1.0	-1.0, 0.0	
Min, Max	-6.0, 7.0	-6.0, 6.0	
Difference in Change from Baseline at Week 12			
n [1]	47	27	
n [2]	37	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.11 [0.37] (-0.86, 0.63)		-0.44 [0.44] (-1.32, 0.44)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.33 [0.58] (-0.82, 1.48)		
MMRM: P-value	0.57		
Corrected Hedges' g (95% CI)	0.144 (-0.358, 0.646)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.62		
Percent Change in Depression at Week 12 from Baseline			
n	25	14	
Mean (SD)	42.2 (188.66)	-46.6 (54.12)	
Median	0.0	-50.0	
Q1, Q3	-66.7, 50.0	-100.0, -33.3	
Min, Max	-100.0, 700.0	-100.0, 100.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7310: Analysis of MPN-SAF Mean Questionnaire Item #10 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 12			
n [1]	32	15	
n [2]	25	14	
MMRM: Least Squares Mean [SE] (95% CI)	26.63 [28.50] (-30.93, 84.20)		-42.88 [40.39] (-124.45, 38.68)
MMRM: Least Squares Mean Difference [SE] (95% CI)	69.52 [49.45] (-30.35, 169.39)		
MMRM: P-value	0.17		
Corrected Hedges' g (95% CI)	0.468 (-0.195, 1.130)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.13		
MPN0110 - Depression at Week 16			
n	48	30	
Mean (SD)	1.8 (2.45)	2.4 (2.89)	
Median	0.5	2.0	
Q1, Q3	0.0, 3.0	0.0, 3.0	
Min, Max	0.0, 8.0	0.0, 10.0	
Return Rate (%)	73%	77%	
Number of Subjects in Risk	56	33	
Return Rate in Risk (%)	86%	91%	
Change in Depression at Week 16 from Baseline			
n	36	26	
Mean (SD)	-0.2 (2.44)	0.2 (2.74)	
Median	0.0	0.0	
Q1, Q3	-1.0, 0.5	-1.0, 1.0	
Min, Max	-6.0, 6.0	-4.0, 10.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7310: Analysis of MPN-SAF Mean Questionnaire Item #10 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	47	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.14 [0.39] (-0.93, 0.64)	0.23 [0.45] (-0.68, 1.13)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.37 [0.60] (-1.56, 0.82)		
MMRM: P-value	0.54		
Corrected Hedges' g (95% CI)	-0.157 (-0.662, 0.349)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.64		
Percent Change in Depression at Week 16 from Baseline			
n	24	14	
Mean (SD)	12.3 (155.04)	-28.8 (55.44)	
Median	-22.5	-33.3	
Q1, Q3	-83.3, 16.7	-50.0, 0.0	
Min, Max	-100.0, 600.0	-100.0, 100.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	32	15	
n [2]	24	14	
MMRM: Least Squares Mean [SE] (95% CI)	16.62 [24.83] (-33.52, 66.77)	-30.45 [33.84] (-98.79, 37.89)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	47.07 [42.00] (-37.75, 131.89)		
MMRM: P-value	0.27		
Corrected Hedges' g (95% CI)	0.373 (-0.291, 1.038)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.31		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7310: Analysis of MPN-SAF Mean Questionnaire Item #10 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
MPN0110 - Depression at Week 20			
n	44	29	
Mean (SD)	1.3 (1.86)	2.1 (2.84)	
Median	0.0	1.0	
Q1, Q3	0.0, 2.0	0.0, 2.0	
Min, Max	0.0, 7.0	0.0, 10.0	
Return Rate (%)	67%	74%	
Number of Subjects in Risk	51	32	
Return Rate in Risk (%)	86%	91%	
Change in Depression at Week 20 from Baseline			
n	32	24	
Mean (SD)	-0.4 (2.08)	-0.5 (1.67)	
Median	0.0	0.0	
Q1, Q3	-1.0, 1.0	-1.0, 0.5	
Min, Max	-6.0, 4.0	-4.0, 2.0	
Difference in Change from Baseline at Week 20			
n [1]	47	27	
n [2]	32	24	
MMRM: Least Squares Mean [SE] (95% CI)	-0.27 [0.31] (-0.90, 0.35)	-0.36 [0.34] (-1.04, 0.32)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.09 [0.46] (-0.83, 1.01)		
MMRM: P-value	0.85		
Corrected Hedges' g (95% CI)	0.050 (-0.480, 0.579)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.49		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7310: Analysis of MPN-SAF Mean Questionnaire Item #10 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in Depression at Week 20 from Baseline			
n	20	13	
Mean (SD)	-22.1 (71.08)	-32.9 (54.83)	
Median	-33.3	-33.3	
Q1, Q3	-90.0, 25.0	-60.0, -20.0	
Min, Max	-100.0, 133.3	-100.0, 100.0	
Difference in Percent Change from Baseline at Week 20			
n [1]	32	15	
n [2]	20	13	
MMRM: Least Squares Mean [SE] (95% CI)	-14.93 [15.60] (-46.43, 16.58)	-35.98 [18.81] (-73.97, 2.01)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	21.05 [24.72] (-28.87, 70.97)		
MMRM: P-value	0.40		
Corrected Hedges' g (95% CI)	0.298 (-0.404, 1.000)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	1.00		
MPN0110 - Depression at Week 24			
n	41	29	
Mean (SD)	1.5 (2.01)	2.4 (3.11)	
Median	0.0	1.0	
Q1, Q3	0.0, 3.0	0.0, 5.0	
Min, Max	0.0, 8.0	0.0, 10.0	
Return Rate (%)	62%	74%	
Number of Subjects in Risk	48	31	
Return Rate in Risk (%)	85%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7310: Analysis of MPN-SAF Mean Questionnaire Item #10 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Depression at Week 24 from Baseline			
n	27	23	
Mean (SD)	-0.3 (2.22)	-0.3 (1.84)	
Median	0.0	0.0	
Q1, Q3	0.0, 1.0	-2.0, 0.0	
Min, Max	-8.0, 2.0	-4.0, 5.0	
Difference in Change from Baseline at Week 24			
n [1]	47	27	
n [2]	27	23	
MMRM: Least Squares Mean [SE] (95% CI)		-0.13 [0.38] (-0.88, 0.62)	-0.18 [0.41] (-1.00, 0.63)
MMRM: Least Squares Mean Difference [SE] (95% CI)		0.06 [0.55] (-1.04, 1.16)	
MMRM: P-value		0.92	
Corrected Hedges' g (95% CI)		0.029 (-0.527, 0.585)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value		0.71	
Percent Change in Depression at Week 24 from Baseline			
n	17	13	
Mean (SD)	12.2 (94.96)	-32.6 (43.47)	
Median	0.0	-33.3	
Q1, Q3	-66.7, 50.0	-66.7, 0.0	
Min, Max	-100.0, 200.0	-100.0, 33.3	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7310: Analysis of MPN-SAF Mean Questionnaire Item #10 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	32	15	
n [2]	17	13	
MMRM: Least Squares Mean [SE] (95% CI)	21.08 [18.93] (-17.14, 59.31)	-34.80 [21.84] (-78.91, 9.31)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	55.88 [29.15] (-3.00, 114.76)		
MMRM: P-value	0.062		
Corrected Hedges' g (95% CI)	0.694 (-0.049, 1.437)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.46		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

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Table 2.7311: Analysis of MPN-SAF Mean Questionnaire Item #11 Score and Change from Baseline

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0111 - Sexual at Baseline		
n	50	29
Mean (SD)	3.6 (3.72)	2.9 (3.81)
Median	3.0	0.0
Q1, Q3	0.0, 7.0	0.0, 6.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
MPN0111 - Sexual at Week 4		
n	60	31
Mean (SD)	4.0 (3.75)	4.0 (3.87)
Median	3.0	3.0
Q1, Q3	0.0, 7.0	0.0, 8.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in Sexual at Week 4 from Baseline		
n	45	26
Mean (SD)	1.0 (3.44)	1.0 (4.11)
Median	0.0	0.0
Q1, Q3	0.0, 1.0	-1.0, 1.0
Min, Max	-9.0, 10.0	-4.0, 10.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7311: Analysis of MPN-SAF Mean Questionnaire Item #11 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	47	27	
n [2]	45	26	
MMRM: Least Squares Mean [SE] (95% CI)	1.30 [0.50] (0.29, 2.31)	0.73 [0.61] (-0.48, 1.94)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.57 [0.79] (-1.00, 2.14)		
MMRM: P-value	0.47		
Corrected Hedges' g (95% CI)	0.171 (-0.313, 0.655)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.17		
Percent Change in Sexual at Week 4 from Baseline			
n	27	12	
Mean (SD)	-1.3 (59.41)	33.9 (211.51)	
Median	0.0	-29.2	
Q1, Q3	-20.0, 0.0	-47.2, 0.0	
Min, Max	-100.0, 250.0	-57.1, 700.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	29	12	
n [2]	27	12	
MMRM: Least Squares Mean [SE] (95% CI)	-14.70 [24.88] (-65.20, 35.80)	24.34 [34.23] (-45.15, 93.82)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-39.04 [40.32] (-120.89, 42.82)		
MMRM: P-value	0.34		
Corrected Hedges' g (95% CI)	-0.303 (-0.986, 0.380)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.098		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7311: Analysis of MPN-SAF Mean Questionnaire Item #11 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0111 - Sexual at Week 8		
n	57	27
Mean (SD)	3.1 (3.54)	2.9 (3.34)
Median	2.0	2.0
Q1, Q3	0.0, 5.0	0.0, 6.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	86%	69%
Number of Subjects in Risk	61	36
Return Rate in Risk (%)	93%	75%
Change in Sexual at Week 8 from Baseline		
n	44	24
Mean (SD)	0.0 (3.50)	0.0 (4.25)
Median	0.0	0.0
Q1, Q3	-1.0, 1.0	-1.5, 0.5
Min, Max	-9.0, 10.0	-10.0, 10.0
Difference in Change from Baseline at Week 8		
n [1]	47	27
n [2]	44	24
MMRM: Least Squares Mean [SE] (95% CI)	0.49 [0.50] (-0.50, 1.48)	0.02 [0.61] (-1.19, 1.22)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.47 [0.78] (-1.08, 2.03)	
MMRM: P-value	0.54	
Corrected Hedges' g (95% CI)	0.147 (-0.351, 0.645)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.65	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7311: Analysis of MPN-SAF Mean Questionnaire Item #11 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Sexual at Week 8 from Baseline		
n	28	11
Mean (SD)	-21.0 (61.71)	-17.2 (79.40)
Median	-12.5	-30.0
Q1, Q3	-85.0, 0.0	-44.4, 0.0
Min, Max	-100.0, 150.0	-100.0, 200.0
Difference in Percent Change from Baseline at Week 8		
n [1]	29	12
n [2]	28	11
MMRM: Least Squares Mean [SE] (95% CI)	-33.29 [22.36] (-78.68, 12.09)	18.43 [30.47] (-43.43, 80.29)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-51.73 [35.50] (-123.79, 20.33)	
MMRM: P-value	0.15	
Corrected Hedges' g (95% CI)	-0.445 (-1.149, 0.260)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.36	
MPN0111 - Sexual at Week 12		
n	51	30
Mean (SD)	3.7 (3.75)	3.3 (3.65)
Median	2.0	2.0
Q1, Q3	0.0, 7.0	0.0, 6.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	77%	77%
Number of Subjects in Risk	59	33
Return Rate in Risk (%)	86%	91%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7311: Analysis of MPN-SAF Mean Questionnaire Item #11 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Sexual at Week 12 from Baseline		
n	37	26
Mean (SD)	1.0 (3.36)	0.4 (4.61)
Median	0.0	0.0
Q1, Q3	0.0, 1.0	-1.0, 3.0
Min, Max	-5.0, 10.0	-10.0, 10.0
Difference in Change from Baseline at Week 12		
n [1]	47	27
n [2]	37	26
MMRM: Least Squares Mean [SE] (95% CI)	1.55 [0.57] (0.41, 2.68)	0.32 [0.66] (-0.99, 1.63)
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.22 [0.87] (-0.50, 2.95)	
MMRM: P-value	0.16	
Corrected Hedges' g (95% CI)	0.353 (-0.152, 0.859)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.28	
Percent Change in Sexual at Week 12 from Baseline		
n	24	11
Mean (SD)	7.1 (79.33)	-20.5 (68.77)
Median	0.0	-33.3
Q1, Q3	-22.2, 8.3	-71.4, 0.0
Min, Max	-100.0, 300.0	-100.0, 150.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7311: Analysis of MPN-SAF Mean Questionnaire Item #11 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 12		
n [1]	29	12
n [2]	24	11
MMRM: Least Squares Mean [SE] (95% CI)	-1.76 [26.06] (-54.66, 51.14)	26.58 [36.49] (-47.50, 100.66)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-28.34 [42.97] (-115.57, 58.89)	
MMRM: P-value	0.51	
Corrected Hedges' g (95% CI)	-0.220 (-0.936, 0.495)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.042	
MPN0111 - Sexual at Week 16		
n	48	30
Mean (SD)	3.3 (3.48)	3.4 (3.44)
Median	2.0	2.5
Q1, Q3	0.0, 5.0	0.0, 6.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	73%	77%
Number of Subjects in Risk	56	33
Return Rate in Risk (%)	86%	91%
Change in Sexual at Week 16 from Baseline		
n	36	26
Mean (SD)	0.1 (4.12)	1.0 (4.42)
Median	0.0	0.0
Q1, Q3	-1.5, 1.0	0.0, 3.0
Min, Max	-10.0, 10.0	-9.0, 10.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7311: Analysis of MPN-SAF Mean Questionnaire Item #11 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	47	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.73 [0.59] (-0.45, 1.92)		0.90 [0.68] (-0.46, 2.27)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.17 [0.90] (-1.97, 1.63)		
MMRM: P-value	0.85		
Corrected Hedges' g (95% CI)	-0.047 (-0.552, 0.457)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.50		
Percent Change in Sexual at Week 16 from Baseline			
n	24	11	
Mean (SD)	-19.0 (68.23)	-6.8 (73.07)	
Median	-14.6	-20.0	
Q1, Q3	-66.7, 0.0	-44.4, 0.0	
Min, Max	-100.0, 200.0	-90.0, 150.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	29	12	
n [2]	24	11	
MMRM: Least Squares Mean [SE] (95% CI)	-32.12 [19.67] (-72.05, 7.81)		8.13 [24.27] (-41.15, 57.41)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-40.25 [28.08] (-97.27, 16.76)		
MMRM: P-value	0.16		
Corrected Hedges' g (95% CI)	-0.428 (-1.149, 0.292)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.60		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.7311: Analysis of MPN-SAF Mean Questionnaire Item #11 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
MPN0111 - Sexual at Week 20			
n	44	29	
Mean (SD)	4.1 (3.51)	3.1 (3.22)	
Median	4.0	2.0	
Q1, Q3	0.0, 6.5	0.0, 5.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	67%	74%	
Number of Subjects in Risk	51	32	
Return Rate in Risk (%)	86%	91%	
Change in Sexual at Week 20 from Baseline			
n	32	24	
Mean (SD)	1.3 (3.53)	0.6 (4.01)	
Median	1.0	0.0	
Q1, Q3	0.0, 3.0	-0.5, 1.5	
Min, Max	-9.0, 9.0	-8.0, 10.0	
Difference in Change from Baseline at Week 20			
n [1]	47	27	
n [2]	32	24	
MMRM: Least Squares Mean [SE] (95% CI)	1.46 [0.56] (0.34, 2.58)	0.42 [0.63] (-0.83, 1.67)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.04 [0.84] (-0.63, 2.71)		
MMRM: P-value	0.22		
Corrected Hedges' g (95% CI)	0.327 (-0.206, 0.859)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.25		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7311: Analysis of MPN-SAF Mean Questionnaire Item #11 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Sexual at Week 20 from Baseline		
n	20	10
Mean (SD)	17.2 (73.71)	2.2 (92.21)
Median	5.6	-17.1
Q1, Q3	0.0, 38.1	-44.4, 0.0
Min, Max	-100.0, 250.0	-80.0, 250.0
Difference in Percent Change from Baseline at Week 20		
n [1]	29	12
n [2]	20	10
MMRM: Least Squares Mean [SE] (95% CI)	-9.93 [21.42] (-53.42, 33.55)	6.83 [27.29] (-48.58, 62.24)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-16.77 [31.88] (-81.50, 47.96)	
MMRM: P-value	0.60	
Corrected Hedges' g (95% CI)	-0.176 (-0.936, 0.585)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.57	
MPN0111 - Sexual at Week 24		
n	41	29
Mean (SD)	3.5 (3.26)	3.5 (3.98)
Median	3.0	2.0
Q1, Q3	0.0, 6.0	0.0, 6.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	62%	74%
Number of Subjects in Risk	48	31
Return Rate in Risk (%)	85%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7311: Analysis of MPN-SAF Mean Questionnaire Item #11 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Sexual at Week 24 from Baseline			
n	27	23	
Mean (SD)	0.7 (3.65)	0.9 (4.85)	
Median	0.0	0.0	
Q1, Q3	0.0, 3.0	-1.0, 3.0	
Min, Max	-9.0, 10.0	-9.0, 10.0	
Difference in Change from Baseline at Week 24			
n [1]	47	27	
n [2]	27	23	
MMRM: Least Squares Mean [SE] (95% CI)	0.80 [0.62] (-0.44, 2.05)	0.67 [0.71] (-0.74, 2.08)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.14 [0.94] (-1.73, 2.01)		
MMRM: P-value	0.88		
Corrected Hedges' g (95% CI)	0.041 (-0.515, 0.598)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.98		
Percent Change in Sexual at Week 24 from Baseline			
n	16	10	
Mean (SD)	-2.9 (56.93)	-6.4 (83.34)	
Median	0.0	-26.7	
Q1, Q3	-30.0, 10.0	-44.4, 25.0	
Min, Max	-100.0, 150.0	-100.0, 200.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7311: Analysis of MPN-SAF Mean Questionnaire Item #11 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	29	12	
n [2]	16	10	
MMRM: Least Squares Mean [SE] (95% CI)	-25.59 [19.93] (-66.05, 14.87)	1.10 [22.99] (-45.57, 47.78)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-26.70 [27.25] (-82.02, 28.62)		
MMRM: P-value	0.33		
Corrected Hedges' g (95% CI)	-0.335 (-1.130, 0.460)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.83		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7312: Analysis of MPN-SAF Mean Questionnaire Item #12 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0112 - Cough at Baseline		
n	50	29
Mean (SD)	2.6 (3.20)	1.6 (2.69)
Median	1.0	1.0
Q1, Q3	0.0, 6.0	0.0, 2.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
MPN0112 - Cough at Week 4		
n	60	31
Mean (SD)	2.1 (2.68)	1.6 (2.60)
Median	1.0	1.0
Q1, Q3	0.0, 3.5	0.0, 2.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in Cough at Week 4 from Baseline		
n	45	26
Mean (SD)	-0.5 (2.91)	-0.3 (1.52)
Median	0.0	0.0
Q1, Q3	-2.0, 1.0	0.0, 0.0
Min, Max	-10.0, 5.0	-6.0, 2.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7312: Analysis of MPN-SAF Mean Questionnaire Item #12 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	47	27	
n [2]	45	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.34 [0.34] (-1.02, 0.34)	-0.58 [0.41] (-1.39, 0.24)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.23 [0.53] (-0.83, 1.29)		
MMRM: P-value	0.66		
Corrected Hedges' g (95% CI)	0.104 (-0.379, 0.587)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.95		
Percent Change in Cough at Week 4 from Baseline			
n	24	14	
Mean (SD)	-26.0 (66.91)	-2.2 (69.90)	
Median	-33.3	0.0	
Q1, Q3	-73.3, 5.6	-50.0, 50.0	
Min, Max	-100.0, 200.0	-100.0, 100.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	26	14	
n [2]	24	14	
MMRM: Least Squares Mean [SE] (95% CI)	-29.46 [16.30] (-62.58, 3.66)	-10.89 [19.46] (-50.43, 28.65)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-18.57 [25.98] (-71.36, 34.22)		
MMRM: P-value	0.48		
Corrected Hedges' g (95% CI)	-0.235 (-0.896, 0.426)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.22		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7312: Analysis of MPN-SAF Mean Questionnaire Item #12 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0112 - Cough at Week 8		
n	57	27
Mean (SD)	2.3 (2.45)	2.3 (3.12)
Median	2.0	1.0
Q1, Q3	0.0, 4.0	0.0, 5.0
Min, Max	0.0, 8.0	0.0, 9.0
Return Rate (%)	86%	69%
Number of Subjects in Risk	61	36
Return Rate in Risk (%)	93%	75%
Change in Cough at Week 8 from Baseline		
n	44	24
Mean (SD)	-0.2 (3.03)	0.5 (2.81)
Median	0.0	0.0
Q1, Q3	-2.0, 1.5	-1.0, 1.0
Min, Max	-8.0, 6.0	-5.0, 8.0
Difference in Change from Baseline at Week 8		
n [1]	47	27
n [2]	44	24
MMRM: Least Squares Mean [SE] (95% CI)	0.03 [0.40] (-0.77, 0.83)	0.16 [0.50] (-0.84, 1.16)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.13 [0.64] (-1.41, 1.15)	
MMRM: P-value	0.84	
Corrected Hedges' g (95% CI)	-0.049 (-0.547, 0.448)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.56	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7312: Analysis of MPN-SAF Mean Questionnaire Item #12 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in Cough at Week 8 from Baseline			
n	24	12	
Mean (SD)	-24.9 (80.58)	-18.8 (77.18)	
Median	-29.2	-10.6	
Q1, Q3	-92.9, 0.0	-100.0, 33.3	
Min, Max	-100.0, 200.0	-100.0, 100.0	
Difference in Percent Change from Baseline at Week 8			
n [1]	26	14	
n [2]	24	12	
MMRM: Least Squares Mean [SE] (95% CI)		-29.07 [19.11] (-67.90, 9.76)	-30.54 [24.62] (-80.58, 19.51)
MMRM: Least Squares Mean Difference [SE] (95% CI)		1.46 [31.55] (-62.66, 65.59)	
MMRM: P-value		0.96	
Corrected Hedges' g (95% CI)		0.016 (-0.677, 0.709)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value		0.94	
MPN0112 - Cough at Week 12			
n	51	30	
Mean (SD)	2.1 (2.69)	2.7 (3.03)	
Median	1.0	2.0	
Q1, Q3	0.0, 4.0	0.0, 5.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	77%	77%	
Number of Subjects in Risk	59	33	
Return Rate in Risk (%)	86%	91%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7312: Analysis of MPN-SAF Mean Questionnaire Item #12 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Cough at Week 12 from Baseline			
n	37	26	
Mean (SD)	-0.3 (3.63)	0.9 (2.14)	
Median	0.0	0.0	
Q1, Q3	-2.0, 1.0	-1.0, 2.0	
Min, Max	-10.0, 10.0	-3.0, 6.0	
Difference in Change from Baseline at Week 12			
n [1]	47	27	
n [2]	37	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.13 [0.44] (-1.00, 0.74)	0.59 [0.51] (-0.42, 1.61)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.72 [0.67] (-2.06, 0.62)		
MMRM: P-value	0.29		
Corrected Hedges' g (95% CI)	-0.271 (-0.775, 0.233)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.10		
Percent Change in Cough at Week 12 from Baseline			
n	20	13	
Mean (SD)	-31.5 (59.04)	56.7 (178.22)	
Median	-41.7	-10.0	
Q1, Q3	-83.3, 8.3	-100.0, 100.0	
Min, Max	-100.0, 100.0	-100.0, 400.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7312: Analysis of MPN-SAF Mean Questionnaire Item #12 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 12		
n [1]	26	14
n [2]	20	13
MMRM: Least Squares Mean [SE] (95% CI)	-31.28 [26.80] (-85.75, 23.18)	50.41 [32.87] (-16.40, 117.21)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-81.69 [42.74] (-168.55, 5.17)	
MMRM: P-value	0.064	
Corrected Hedges' g (95% CI)	-0.668 (-1.384, 0.049)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.13	
MPN0112 - Cough at Week 16		
n	48	30
Mean (SD)	1.9 (2.59)	1.3 (2.31)
Median	1.0	0.5
Q1, Q3	0.0, 2.0	0.0, 2.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	73%	77%
Number of Subjects in Risk	56	33
Return Rate in Risk (%)	86%	91%
Change in Cough at Week 16 from Baseline		
n	36	26
Mean (SD)	-0.6 (2.96)	-0.2 (1.44)
Median	0.0	0.0
Q1, Q3	-1.5, 1.0	-1.0, 0.0
Min, Max	-10.0, 4.0	-5.0, 2.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7312: Analysis of MPN-SAF Mean Questionnaire Item #12 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	47	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.14 [0.37] (-0.89, 0.60)	-0.49 [0.42] (-1.33, 0.35)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.34 [0.56] (-0.78, 1.47)		
MMRM: P-value	0.55		
Corrected Hedges' g (95% CI)	0.154 (-0.352, 0.659)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.56		
Percent Change in Cough at Week 16 from Baseline			
n	20	13	
Mean (SD)	-30.1 (61.77)	-2.5 (105.36)	
Median	-33.3	-33.3	
Q1, Q3	-87.5, 0.0	-71.4, 0.0	
Min, Max	-100.0, 100.0	-100.0, 200.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	26	14	
n [2]	20	13	
MMRM: Least Squares Mean [SE] (95% CI)	-35.63 [20.01] (-76.29, 5.03)	-8.97 [23.89] (-57.51, 39.58)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-26.67 [31.52] (-90.71, 37.38)		
MMRM: P-value	0.40		
Corrected Hedges' g (95% CI)	-0.295 (-0.997, 0.407)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.48		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7312: Analysis of MPN-SAF Mean Questionnaire Item #12 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
MPN0112 - Cough at Week 20			
n	44	29	
Mean (SD)	2.0 (2.26)	1.6 (2.57)	
Median	1.0	0.0	
Q1, Q3	0.0, 3.0	0.0, 3.0	
Min, Max	0.0, 9.0	0.0, 9.0	
Return Rate (%)	67%	74%	
Number of Subjects in Risk	51	32	
Return Rate in Risk (%)	86%	91%	
Change in Cough at Week 20 from Baseline			
n	32	24	
Mean (SD)	-0.5 (2.90)	0.2 (1.83)	
Median	0.0	0.0	
Q1, Q3	-2.0, 1.5	-1.0, 0.0	
Min, Max	-8.0, 5.0	-4.0, 4.0	
Difference in Change from Baseline at Week 20			
n [1]	47	27	
n [2]	32	24	
MMRM: Least Squares Mean [SE] (95% CI)	0.01 [0.41] (-0.82, 0.83)	-0.12 [0.45] (-1.03, 0.78)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.13 [0.62] (-1.10, 1.36)		
MMRM: P-value	0.83		
Corrected Hedges' g (95% CI)	0.057 (-0.472, 0.586)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.59		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7312: Analysis of MPN-SAF Mean Questionnaire Item #12 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Cough at Week 20 from Baseline		
n	19	13
Mean (SD)	-28.5 (71.78)	57.2 (174.18)
Median	-33.3	-10.0
Q1, Q3	-83.3, 0.0	-50.0, 133.3
Min, Max	-100.0, 200.0	-100.0, 400.0
Difference in Percent Change from Baseline at Week 20		
n [1]	26	14
n [2]	19	13
MMRM: Least Squares Mean [SE] (95% CI)	-25.40 [29.92] (-86.20, 35.41)	48.38 [35.73] (-24.24, 121.00)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-73.77 [46.93] (-169.15, 21.60)	
MMRM: P-value	0.13	
Corrected Hedges' g (95% CI)	-0.554 (-1.273, 0.164)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.83	
MPN0112 - Cough at Week 24		
n	41	29
Mean (SD)	1.8 (2.25)	1.0 (2.47)
Median	1.0	0.0
Q1, Q3	0.0, 3.0	0.0, 1.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	62%	74%
Number of Subjects in Risk	48	31
Return Rate in Risk (%)	85%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7312: Analysis of MPN-SAF Mean Questionnaire Item #12 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Cough at Week 24 from Baseline			
n	27	23	
Mean (SD)	-0.6 (3.55)	-0.6 (1.56)	
Median	0.0	0.0	
Q1, Q3	-3.0, 1.0	-1.0, 0.0	
Min, Max	-8.0, 9.0	-5.0, 3.0	
Difference in Change from Baseline at Week 24			
n [1]	47	27	
n [2]	27	23	
MMRM: Least Squares Mean [SE] (95% CI)	0.00 [0.45] (-0.90, 0.91)	-0.86 [0.50] (-1.87, 0.14)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.87 [0.68] (-0.48, 2.22)		
MMRM: P-value	0.20		
Corrected Hedges' g (95% CI)	0.359 (-0.201, 0.920)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.87		
Percent Change in Cough at Week 24 from Baseline			
n	15	13	
Mean (SD)	-23.9 (97.61)	-60.5 (60.98)	
Median	-50.0	-100.0	
Q1, Q3	-100.0, 0.0	-100.0, -50.0	
Min, Max	-100.0, 200.0	-100.0, 100.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7312: Analysis of MPN-SAF Mean Questionnaire Item #12 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	26	14	
n [2]	15	13	
MMRM: Least Squares Mean [SE] (95% CI)	-19.66 [23.31] (-67.03, 27.71)	-69.25 [24.91] (-119.87, -18.63)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	49.59 [34.69] (-20.91, 120.09)		
MMRM: P-value	0.16		
Corrected Hedges' g (95% CI)	0.535 (-0.221, 1.290)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.84		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.7313: Analysis of MPN-SAF Mean Questionnaire Item #13 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0113 - Night Sweats at Baseline		
n	50	29
Mean (SD)	2.7 (2.64)	3.2 (3.45)
Median	2.0	2.0
Q1, Q3	0.0, 5.0	0.0, 7.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
MPN0113 - Night Sweats at Week 4		
n	60	31
Mean (SD)	2.1 (2.55)	3.4 (3.54)
Median	1.0	2.0
Q1, Q3	0.0, 3.0	0.0, 8.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in Night Sweats at Week 4 from Baseline		
n	45	26
Mean (SD)	-0.5 (2.31)	0.1 (2.02)
Median	0.0	0.0
Q1, Q3	-2.0, 0.0	-1.0, 1.0
Min, Max	-6.0, 6.0	-5.0, 5.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7313: Analysis of MPN-SAF Mean Questionnaire Item #13 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	47	27	
n [2]	45	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.56 [0.32] (-1.20, 0.08)	0.31 [0.39] (-0.47, 1.09)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.87 [0.50] (-1.88, 0.14)		
MMRM: P-value	0.089		
Corrected Hedges' g (95% CI)	-0.410 (-0.897, 0.078)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.12		
Percent Change in Night Sweats at Week 4 from Baseline			
n	30	17	
Mean (SD)	-14.2 (99.56)	1.7 (71.97)	
Median	-33.3	0.0	
Q1, Q3	-83.3, 0.0	-50.0, 14.3	
Min, Max	-100.0, 300.0	-100.0, 166.7	
Difference in Percent Change from Baseline at Week 4			
n [1]	31	17	
n [2]	30	17	
MMRM: Least Squares Mean [SE] (95% CI)	-17.83 [16.94] (-52.01, 16.35)	3.74 [22.34] (-41.34, 48.82)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-21.57 [28.02] (-78.11, 34.98)		
MMRM: P-value	0.45		
Corrected Hedges' g (95% CI)	-0.229 (-0.826, 0.368)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.036		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7313: Analysis of MPN-SAF Mean Questionnaire Item #13 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0113 - Night Sweats at Week 8		
n	57	27
Mean (SD)	1.7 (2.03)	2.9 (3.05)
Median	1.0	2.0
Q1, Q3	0.0, 3.0	0.0, 6.0
Min, Max	0.0, 8.0	0.0, 10.0
Return Rate (%)	86%	69%
Number of Subjects in Risk	61	36
Return Rate in Risk (%)	93%	75%
Change in Night Sweats at Week 8 from Baseline		
n	44	24
Mean (SD)	-0.9 (2.45)	0.0 (2.18)
Median	-1.0	0.0
Q1, Q3	-2.0, 0.0	-1.0, 1.0
Min, Max	-6.0, 7.0	-4.0, 5.0
Difference in Change from Baseline at Week 8		
n [1]	47	27
n [2]	44	24
MMRM: Least Squares Mean [SE] (95% CI)	-0.75 [0.33] (-1.40, -0.10)	0.11 [0.40] (-0.69, 0.90)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.86 [0.51] (-1.88, 0.17)	
MMRM: P-value	0.10	
Corrected Hedges' g (95% CI)	-0.403 (-0.905, 0.099)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.017	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7313: Analysis of MPN-SAF Mean Questionnaire Item #13 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in Night Sweats at Week 8 from Baseline			
n	28	15	
Mean (SD)	-46.7 (42.56)	-8.1 (53.29)	
Median	-50.0	-14.3	
Q1, Q3	-80.4, -26.7	-50.0, 33.3	
Min, Max	-100.0, 66.7	-100.0, 100.0	
Difference in Percent Change from Baseline at Week 8			
n [1]	31	17	
n [2]	28	15	
MMRM: Least Squares Mean [SE] (95% CI)	-40.01 [11.71] (-63.64, -16.39)	-8.62 [15.09] (-39.07, 21.83)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-31.39 [18.96] (-69.66, 6.88)		
MMRM: P-value	0.11		
Corrected Hedges' g (95% CI)	-0.507 (-1.143, 0.129)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.019		
MPN0113 - Night Sweats at Week 12			
n	51	30	
Mean (SD)	1.4 (1.88)	2.6 (2.92)	
Median	1.0	1.5	
Q1, Q3	0.0, 2.0	0.0, 4.0	
Min, Max	0.0, 8.0	0.0, 10.0	
Return Rate (%)	77%	77%	
Number of Subjects in Risk	59	33	
Return Rate in Risk (%)	86%	91%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7313: Analysis of MPN-SAF Mean Questionnaire Item #13 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Night Sweats at Week 12 from Baseline			
n	37	26	
Mean (SD)	-1.2 (2.52)	-0.4 (2.48)	
Median	-1.0	0.0	
Q1, Q3	-3.0, 0.0	-1.0, 1.0	
Min, Max	-6.0, 5.0	-6.0, 4.0	
Difference in Change from Baseline at Week 12			
n [1]	47	27	
n [2]	37	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.89 [0.36] (-1.61, -0.18)	-0.28 [0.43] (-1.13, 0.58)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.62 [0.56] (-1.73, 0.49)		
MMRM: P-value	0.27		
Corrected Hedges' g (95% CI)	-0.279 (-0.783, 0.225)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.006		
Percent Change in Night Sweats at Week 12 from Baseline			
n	24	16	
Mean (SD)	-52.8 (57.44)	-8.7 (73.69)	
Median	-57.1	-41.4	
Q1, Q3	-100.0, -33.3	-55.0, 29.2	
Min, Max	-100.0, 166.7	-100.0, 200.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7313: Analysis of MPN-SAF Mean Questionnaire Item #13 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 12		
n [1]	31	17
n [2]	24	16
MMRM: Least Squares Mean [SE] (95% CI)	-39.83 [15.24] (-70.58, -9.08)	-7.61 [19.71] (-47.40, 32.17)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-32.21 [24.84] (-82.35, 17.92)	
MMRM: P-value	0.20	
Corrected Hedges' g (95% CI)	-0.414 (-1.053, 0.225)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.004	
MPN0113 - Night Sweats at Week 16		
n	48	30
Mean (SD)	1.2 (1.77)	2.4 (2.98)
Median	0.0	1.0
Q1, Q3	0.0, 2.0	0.0, 4.0
Min, Max	0.0, 8.0	0.0, 10.0
Return Rate (%)	73%	77%
Number of Subjects in Risk	56	33
Return Rate in Risk (%)	86%	91%
Change in Night Sweats at Week 16 from Baseline		
n	36	26
Mean (SD)	-1.6 (2.34)	-0.3 (2.91)
Median	-1.0	0.0
Q1, Q3	-2.5, 0.0	-1.0, 1.0
Min, Max	-8.0, 2.0	-10.0, 5.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7313: Analysis of MPN-SAF Mean Questionnaire Item #13 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	47	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	-1.12 [0.37] (-1.86, -0.39)	-0.16 [0.44] (-1.03, 0.70)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.96 [0.57] (-2.09, 0.17)		
MMRM: P-value	0.096		
Corrected Hedges' g (95% CI)	-0.427 (-0.937, 0.083)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.003		
Percent Change in Night Sweats at Week 16 from Baseline			
n	22	16	
Mean (SD)	-64.6 (35.62)	-10.8 (78.15)	
Median	-76.4	-20.0	
Q1, Q3	-100.0, -40.0	-56.3, 19.6	
Min, Max	-100.0, 0.0	-100.0, 200.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	31	17	
n [2]	22	16	
MMRM: Least Squares Mean [SE] (95% CI)	-41.22 [15.53] (-72.56, -9.88)	-9.75 [19.95] (-50.01, 30.52)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-31.47 [25.21] (-82.35, 19.41)		
MMRM: P-value	0.22		
Corrected Hedges' g (95% CI)	-0.406 (-1.057, 0.244)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.005		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7313: Analysis of MPN-SAF Mean Questionnaire Item #13 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0113 - Night Sweats at Week 20		
n	44	29
Mean (SD)	0.9 (1.44)	2.5 (2.98)
Median	0.0	1.0
Q1, Q3	0.0, 1.5	0.0, 4.0
Min, Max	0.0, 6.0	0.0, 10.0
Return Rate (%)	67%	74%
Number of Subjects in Risk	51	32
Return Rate in Risk (%)	86%	91%
Change in Night Sweats at Week 20 from Baseline		
n	32	24
Mean (SD)	-1.5 (2.60)	-0.5 (2.89)
Median	-0.5	0.0
Q1, Q3	-3.5, 0.0	-1.5, 1.0
Min, Max	-9.0, 3.0	-8.0, 4.0
Difference in Change from Baseline at Week 20		
n [1]	47	27
n [2]	32	24
MMRM: Least Squares Mean [SE] (95% CI)	-1.19 [0.39] (-1.97, -0.41)	-0.30 [0.46] (-1.21, 0.61)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.89 [0.60] (-2.08, 0.31)	
MMRM: P-value	0.14	
Corrected Hedges' g (95% CI)	-0.394 (-0.929, 0.140)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.029	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7313: Analysis of MPN-SAF Mean Questionnaire Item #13 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Night Sweats at Week 20 from Baseline		
n	18	16
Mean (SD)	-76.0 (38.07)	-12.0 (78.98)
Median	-100.0	-31.4
Q1, Q3	-100.0, -60.0	-71.3, 12.5
Min, Max	-100.0, 20.0	-100.0, 150.0
Difference in Percent Change from Baseline at Week 20		
n [1]	31	17
n [2]	18	16
MMRM: Least Squares Mean [SE] (95% CI)	-44.01 [16.40] (-77.10, -10.92)	-10.95 [20.67] (-52.67, 30.77)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-33.06 [26.33] (-86.20, 20.08)	
MMRM: P-value	0.22	
Corrected Hedges' g (95% CI)	-0.425 (-1.106, 0.256)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.002	
MPN0113 - Night Sweats at Week 24		
n	41	29
Mean (SD)	1.2 (1.90)	2.9 (3.29)
Median	0.0	2.0
Q1, Q3	0.0, 2.0	0.0, 4.0
Min, Max	0.0, 8.0	0.0, 10.0
Return Rate (%)	62%	74%
Number of Subjects in Risk	48	31
Return Rate in Risk (%)	85%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7313: Analysis of MPN-SAF Mean Questionnaire Item #13 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Night Sweats at Week 24 from Baseline			
n	27	23	
Mean (SD)	-1.5 (1.99)	-0.3 (2.36)	
Median	-1.0	0.0	
Q1, Q3	-3.0, 0.0	-1.0, 1.0	
Min, Max	-7.0, 1.0	-8.0, 4.0	
Difference in Change from Baseline at Week 24			
n [1]	47	27	
n [2]	27	23	
MMRM: Least Squares Mean [SE] (95% CI)		-1.10 [0.32] (-1.75, -0.46)	-0.21 [0.35] (-0.92, 0.49)
MMRM: Least Squares Mean Difference [SE] (95% CI)		-0.89 [0.48] (-1.84, 0.06)	
MMRM: P-value		0.066	
Corrected Hedges' g (95% CI)		-0.518 (-1.083, 0.047)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value		0.004	
Percent Change in Night Sweats at Week 24 from Baseline			
n	17	15	
Mean (SD)	-63.2 (41.19)	-20.4 (46.92)	
Median	-75.0	0.0	
Q1, Q3	-100.0, -33.3	-50.0, 14.3	
Min, Max	-100.0, 20.0	-100.0, 50.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7313: Analysis of MPN-SAF Mean Questionnaire Item #13 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	31	17	
n [2]	17	15	
MMRM: Least Squares Mean [SE] (95% CI)	-51.93 [10.82] (-73.77, -30.08)	-22.07 [12.24] (-46.78, 2.63)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-29.85 [16.21] (-62.57, 2.87)		
MMRM: P-value	0.073		
Corrected Hedges' g (95% CI)	-0.633 (-1.345, 0.078)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.012		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.7314: Analysis of MPN-SAF Mean Questionnaire Item #14 Score and Change from Baseline

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0114 - Itching at Baseline		
n	50	29
Mean (SD)	1.4 (2.00)	1.8 (2.57)
Median	0.0	0.0
Q1, Q3	0.0, 2.0	0.0, 3.0
Min, Max	0.0, 7.0	0.0, 9.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
MPN0114 - Itching at Week 4		
n	60	31
Mean (SD)	1.4 (2.04)	1.5 (1.91)
Median	0.0	1.0
Q1, Q3	0.0, 2.0	0.0, 2.0
Min, Max	0.0, 9.0	0.0, 8.0
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in Itching at Week 4 from Baseline		
n	45	26
Mean (SD)	0.1 (1.45)	0.0 (1.91)
Median	0.0	0.0
Q1, Q3	0.0, 1.0	-1.0, 1.0
Min, Max	-4.0, 3.0	-7.0, 3.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7314: Analysis of MPN-SAF Mean Questionnaire Item #14 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	47	27	
n [2]	45	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.00 [0.22] (-0.44, 0.45)	-0.03 [0.27] (-0.57, 0.51)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.03 [0.35] (-0.66, 0.73)		
MMRM: P-value	0.93		
Corrected Hedges' g (95% CI)	0.021 (-0.462, 0.504)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.98		
Percent Change in Itching at Week 4 from Baseline			
n	20	11	
Mean (SD)	-0.1 (97.40)	-22.4 (56.02)	
Median	0.0	-33.3	
Q1, Q3	-83.3, 33.3	-50.0, 0.0	
Min, Max	-100.0, 300.0	-100.0, 100.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	22	12	
n [2]	20	11	
MMRM: Least Squares Mean [SE] (95% CI)	-10.02 [19.76] (-50.49, 30.45)	-29.74 [24.51] (-79.94, 20.46)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	19.72 [32.28] (-46.40, 85.85)		
MMRM: P-value	0.55		
Corrected Hedges' g (95% CI)	0.223 (-0.514, 0.961)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.14		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7314: Analysis of MPN-SAF Mean Questionnaire Item #14 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
MPN0114 - Itching at Week 8			
n	57	27	
Mean (SD)	1.4 (2.01)	1.4 (1.97)	
Median	0.0	1.0	
Q1, Q3	0.0, 2.0	0.0, 2.0	
Min, Max	0.0, 8.0	0.0, 7.0	
Return Rate (%)	86%	69%	
Number of Subjects in Risk	61	36	
Return Rate in Risk (%)	93%	75%	
Change in Itching at Week 8 from Baseline			
n	44	24	
Mean (SD)	0.2 (1.84)	-0.3 (2.06)	
Median	0.0	0.0	
Q1, Q3	0.0, 1.0	-0.5, 1.0	
Min, Max	-5.0, 5.0	-7.0, 2.0	
Difference in Change from Baseline at Week 8			
n [1]	47	27	
n [2]	44	24	
MMRM: Least Squares Mean [SE] (95% CI)	0.11 [0.25] (-0.38, 0.61)	-0.25 [0.31] (-0.87, 0.36)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.37 [0.39] (-0.42, 1.15)		
MMRM: P-value	0.36		
Corrected Hedges' g (95% CI)	0.226 (-0.273, 0.725)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.96		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7314: Analysis of MPN-SAF Mean Questionnaire Item #14 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Itching at Week 8 from Baseline		
n	20	10
Mean (SD)	-2.7 (133.98)	-37.7 (52.33)
Median	-12.5	-44.4
Q1, Q3	-100.0, 0.0	-77.8, 0.0
Min, Max	-100.0, 500.0	-100.0, 40.0
Difference in Percent Change from Baseline at Week 8		
n [1]	22	12
n [2]	20	10
MMRM: Least Squares Mean [SE] (95% CI)	-11.15 [25.73] (-63.86, 41.57)	-32.78 [33.60] (-101.61, 36.05)
MMRM: Least Squares Mean Difference [SE] (95% CI)	21.63 [42.81] (-66.05, 109.32)	
MMRM: P-value	0.62	
Corrected Hedges' g (95% CI)	0.187 (-0.573, 0.948)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.35	
MPN0114 - Itching at Week 12		
n	51	30
Mean (SD)	1.4 (2.00)	1.6 (2.13)
Median	0.0	1.0
Q1, Q3	0.0, 2.0	0.0, 3.0
Min, Max	0.0, 9.0	0.0, 8.0
Return Rate (%)	77%	77%
Number of Subjects in Risk	59	33
Return Rate in Risk (%)	86%	91%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7314: Analysis of MPN-SAF Mean Questionnaire Item #14 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Itching at Week 12 from Baseline			
n	37	26	
Mean (SD)	0.3 (2.18)	0.0 (2.58)	
Median	0.0	0.0	
Q1, Q3	0.0, 1.0	-1.0, 1.0	
Min, Max	-5.0, 6.0	-9.0, 5.0	
Difference in Change from Baseline at Week 12			
n [1]	47	27	
n [2]	37	26	
MMRM: Least Squares Mean [SE] (95% CI)		0.00 [0.32] (-0.64, 0.63)	0.07 [0.40] (-0.72, 0.87)
MMRM: Least Squares Mean Difference [SE] (95% CI)		-0.08 [0.51] (-1.09, 0.94)	
MMRM: P-value		0.88	
Corrected Hedges' g (95% CI)		-0.038 (-0.539, 0.464)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value		0.42	
Percent Change in Itching at Week 12 from Baseline			
n	18	12	
Mean (SD)	22.0 (169.83)	-19.8 (67.00)	
Median	-25.0	-18.1	
Q1, Q3	-100.0, 100.0	-87.5, 36.7	
Min, Max	-100.0, 600.0	-100.0, 100.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7314: Analysis of MPN-SAF Mean Questionnaire Item #14 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 12		
n [1]	22	12
n [2]	18	12
MMRM: Least Squares Mean [SE] (95% CI)	1.78 [31.23] (-62.19, 65.75)	-26.31 [40.27] (-108.80, 56.17)
MMRM: Least Squares Mean Difference [SE] (95% CI)	28.10 [51.39] (-77.18, 133.37)	
MMRM: P-value	0.59	
Corrected Hedges' g (95% CI)	0.202 (-0.530, 0.934)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.56	
MPN0114 - Itching at Week 16		
n	48	30
Mean (SD)	1.2 (1.80)	1.6 (2.06)
Median	0.0	1.0
Q1, Q3	0.0, 2.0	0.0, 3.0
Min, Max	0.0, 9.0	0.0, 8.0
Return Rate (%)	73%	77%
Number of Subjects in Risk	56	33
Return Rate in Risk (%)	86%	91%
Change in Itching at Week 16 from Baseline		
n	36	26
Mean (SD)	0.0 (2.00)	-0.1 (1.86)
Median	0.0	0.0
Q1, Q3	0.0, 0.5	0.0, 1.0
Min, Max	-6.0, 3.0	-6.0, 4.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7314: Analysis of MPN-SAF Mean Questionnaire Item #14 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	47	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.09 [0.28] (-0.47, 0.65)	-0.03 [0.33] (-0.69, 0.62)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.12 [0.43] (-0.73, 0.98)		
MMRM: P-value	0.78		
Corrected Hedges' g (95% CI)	0.073 (-0.432, 0.577)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.81		
Percent Change in Itching at Week 16 from Baseline			
n	16	12	
Mean (SD)	-30.2 (59.28)	26.4 (132.19)	
Median	-14.3	-5.6	
Q1, Q3	-85.7, 0.0	-50.0, 60.0	
Min, Max	-100.0, 100.0	-100.0, 400.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	22	12	
n [2]	16	12	
MMRM: Least Squares Mean [SE] (95% CI)	-25.71 [22.96] (-72.75, 21.32)	19.94 [25.23] (-31.75, 71.63)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-45.65 [34.73] (-116.78, 25.48)		
MMRM: P-value	0.20		
Corrected Hedges' g (95% CI)	-0.492 (-1.252, 0.267)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.28		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7314: Analysis of MPN-SAF Mean Questionnaire Item #14 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0114 - Itching at Week 20		
n	44	29
Mean (SD)	1.0 (1.44)	2.1 (2.77)
Median	0.0	1.0
Q1, Q3	0.0, 2.0	0.0, 3.0
Min, Max	0.0, 6.0	0.0, 10.0
Return Rate (%)	67%	74%
Number of Subjects in Risk	51	32
Return Rate in Risk (%)	86%	91%
Change in Itching at Week 20 from Baseline		
n	32	24
Mean (SD)	-0.1 (2.41)	0.4 (1.64)
Median	0.0	0.0
Q1, Q3	-1.0, 0.5	0.0, 1.0
Min, Max	-6.0, 6.0	-4.0, 4.0
Difference in Change from Baseline at Week 20		
n [1]	47	27
n [2]	32	24
MMRM: Least Squares Mean [SE] (95% CI)	0.18 [0.33] (-0.49, 0.85)	0.50 [0.39] (-0.28, 1.28)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.32 [0.51] (-1.35, 0.70)	
MMRM: P-value	0.53	
Corrected Hedges' g (95% CI)	-0.166 (-0.697, 0.364)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.12	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7314: Analysis of MPN-SAF Mean Questionnaire Item #14 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Itching at Week 20 from Baseline		
n	13	12
Mean (SD)	-60.5 (41.08)	38.3 (127.64)
Median	-66.7	0.0
Q1, Q3	-100.0, -25.0	-12.5, 70.0
Min, Max	-100.0, 0.0	-100.0, 400.0
Difference in Percent Change from Baseline at Week 20		
n [1]	22	12
n [2]	13	12
MMRM: Least Squares Mean [SE] (95% CI)	-36.32 [22.63] (-82.68, 10.03)	31.79 [24.10] (-17.57, 81.15)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-68.11 [33.72] (-137.18, 0.96)	
MMRM: P-value	0.053	
Corrected Hedges' g (95% CI)	-0.798 (-1.614, 0.017)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.021	
MPN0114 - Itching at Week 24		
n	41	29
Mean (SD)	0.9 (1.20)	2.4 (2.96)
Median	0.0	2.0
Q1, Q3	0.0, 2.0	0.0, 3.0
Min, Max	0.0, 4.0	0.0, 10.0
Return Rate (%)	62%	74%
Number of Subjects in Risk	48	31
Return Rate in Risk (%)	85%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7314: Analysis of MPN-SAF Mean Questionnaire Item #14 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Itching at Week 24 from Baseline			
n	27	23	
Mean (SD)	0.0 (1.76)	0.5 (1.93)	
Median	0.0	0.0	
Q1, Q3	-1.0, 1.0	0.0, 1.0	
Min, Max	-5.0, 3.0	-4.0, 7.0	
Difference in Change from Baseline at Week 24			
n [1]	47	27	
n [2]	27	23	
MMRM: Least Squares Mean [SE] (95% CI)		0.10 [0.30] (-0.51, 0.70)	0.58 [0.34] (-0.09, 1.26)
MMRM: Least Squares Mean Difference [SE] (95% CI)		-0.49 [0.45] (-1.39, 0.42)	
MMRM: P-value	0.29		
Corrected Hedges' g (95% CI)	-0.300 (-0.859, 0.259)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.19		
Percent Change in Itching at Week 24 from Baseline			
n	10	12	
Mean (SD)	-49.6 (35.96)	57.5 (207.73)	
Median	-50.0	0.0	
Q1, Q3	-71.4, -25.0	-5.6, 25.6	
Min, Max	-100.0, 0.0	-100.0, 700.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7314: Analysis of MPN-SAF Mean Questionnaire Item #14 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 24		
n [1]	22	12
n [2]	10	12
MMRM: Least Squares Mean [SE] (95% CI)	-49.50 [34.91] (-121.00, 22.00)	51.00 [38.17] (-27.18, 129.18)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-100.50 [52.15] (-207.34, 6.33)	
MMRM: P-value	0.064	
Corrected Hedges' g (95% CI)	-0.787 (-1.658, 0.084)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.028	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

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Table 2.7315: Analysis of MPN-SAF Mean Questionnaire Item #15 Score and Change from Baseline

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0115 - Bone Pain at Baseline		
n	50	29
Mean (SD)	2.1 (2.70)	2.9 (2.77)
Median	1.0	3.0
Q1, Q3	0.0, 5.0	0.0, 5.0
Min, Max	0.0, 9.0	0.0, 9.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
MPN0115 - Bone Pain at Week 4		
n	60	31
Mean (SD)	2.1 (2.70)	3.0 (3.51)
Median	1.0	1.0
Q1, Q3	0.0, 3.0	0.0, 7.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in Bone Pain at Week 4 from Baseline		
n	45	26
Mean (SD)	0.2 (1.60)	0.5 (2.18)
Median	0.0	0.0
Q1, Q3	0.0, 1.0	0.0, 2.0
Min, Max	-3.0, 5.0	-3.0, 6.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7315: Analysis of MPN-SAF Mean Questionnaire Item #15 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	47	27	
n [2]	45	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.10 [0.31] (-0.51, 0.71)	0.54 [0.37] (-0.18, 1.27)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.44 [0.47] (-1.39, 0.51)		
MMRM: P-value	0.35		
Corrected Hedges' g (95% CI)	-0.221 (-0.705, 0.264)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.65		
Percent Change in Bone Pain at Week 4 from Baseline			
n	23	15	
Mean (SD)	4.9 (97.54)	0.8 (75.21)	
Median	0.0	0.0	
Q1, Q3	-42.9, 20.0	-66.7, 33.3	
Min, Max	-100.0, 300.0	-100.0, 200.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	24	16	
n [2]	23	15	
MMRM: Least Squares Mean [SE] (95% CI)	-3.06 [21.19] (-46.12, 40.00)	-5.33 [25.41] (-56.97, 46.30)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	2.27 [31.58] (-61.91, 66.45)		
MMRM: P-value	0.94		
Corrected Hedges' g (95% CI)	0.022 (-0.628, 0.673)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.63		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.7315: Analysis of MPN-SAF Mean Questionnaire Item #15 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
MPN0115 - Bone Pain at Week 8			
n	57	27	
Mean (SD)	2.1 (2.41)	2.8 (3.33)	
Median	1.0	1.0	
Q1, Q3	0.0, 3.0	0.0, 6.0	
Min, Max	0.0, 8.0	0.0, 9.0	
Return Rate (%)	86%	69%	
Number of Subjects in Risk	61	36	
Return Rate in Risk (%)	93%	75%	
Change in Bone Pain at Week 8 from Baseline			
n	44	24	
Mean (SD)	0.2 (1.67)	0.4 (2.08)	
Median	0.0	0.0	
Q1, Q3	-1.0, 1.0	-0.5, 1.0	
Min, Max	-4.0, 3.0	-3.0, 6.0	
Difference in Change from Baseline at Week 8			
n [1]	47	27	
n [2]	44	24	
MMRM: Least Squares Mean [SE] (95% CI)		0.12 [0.29] (-0.46, 0.70)	0.66 [0.34] (-0.03, 1.35)
MMRM: Least Squares Mean Difference [SE] (95% CI)		-0.54 [0.45] (-1.43, 0.35)	
MMRM: P-value	0.23		
Corrected Hedges' g (95% CI)	-0.290 (-0.789, 0.210)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.70		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn15-rt.pdf 24AUG2023:17:01

Table 2.7315: Analysis of MPN-SAF Mean Questionnaire Item #15 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in Bone Pain at Week 8 from Baseline			
n	23	13	
Mean (SD)	3.3 (95.39)	0.9 (65.03)	
Median	-14.3	0.0	
Q1, Q3	-50.0, 40.0	-33.3, 33.3	
Min, Max	-100.0, 300.0	-100.0, 166.7	
Difference in Percent Change from Baseline at Week 8			
n [1]	24	16	
n [2]	23	13	
MMRM: Least Squares Mean [SE] (95% CI)	-6.83 [19.10] (-45.64, 31.98)	10.40 [23.22] (-36.78, 57.58)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-17.23 [28.38] (-74.90, 40.44)		
MMRM: P-value	0.55		
Corrected Hedges' g (95% CI)	-0.190 (-0.871, 0.492)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.66		
MPN0115 - Bone Pain at Week 12			
n	51	30	
Mean (SD)	1.7 (2.29)	2.9 (3.36)	
Median	0.0	1.5	
Q1, Q3	0.0, 3.0	0.0, 5.0	
Min, Max	0.0, 9.0	0.0, 10.0	
Return Rate (%)	77%	77%	
Number of Subjects in Risk	59	33	
Return Rate in Risk (%)	86%	91%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.7315: Analysis of MPN-SAF Mean Questionnaire Item #15 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Bone Pain at Week 12 from Baseline			
n	37	26	
Mean (SD)	0.2 (1.97)	0.4 (2.42)	
Median	0.0	0.0	
Q1, Q3	0.0, 1.0	0.0, 1.0	
Min, Max	-4.0, 4.0	-6.0, 5.0	
Difference in Change from Baseline at Week 12			
n [1]	47	27	
n [2]	37	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.02 [0.34] (-0.70, 0.66)	0.64 [0.41] (-0.17, 1.45)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.66 [0.53] (-1.71, 0.39)		
MMRM: P-value	0.21		
Corrected Hedges' g (95% CI)	-0.315 (-0.820, 0.189)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.20		
Percent Change in Bone Pain at Week 12 from Baseline			
n	17	15	
Mean (SD)	17.7 (120.79)	4.1 (68.31)	
Median	0.0	0.0	
Q1, Q3	-57.1, 50.0	-42.9, 50.0	
Min, Max	-100.0, 300.0	-100.0, 166.7	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7315: Analysis of MPN-SAF Mean Questionnaire Item #15 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 12		
n [1]	24	16
n [2]	17	15
MMRM: Least Squares Mean [SE] (95% CI)	-7.25 [21.56] (-51.08, 36.57)	10.31 [25.72] (-41.96, 62.59)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-17.57 [32.05] (-82.70, 47.57)	
MMRM: P-value	0.59	
Corrected Hedges' g (95% CI)	-0.182 (-0.878, 0.514)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.63	
MPN0115 - Bone Pain at Week 16		
n	48	30
Mean (SD)	1.8 (2.17)	2.8 (3.21)
Median	1.0	1.5
Q1, Q3	0.0, 3.0	0.0, 6.0
Min, Max	0.0, 8.0	0.0, 9.0
Return Rate (%)	73%	77%
Number of Subjects in Risk	56	33
Return Rate in Risk (%)	86%	91%
Change in Bone Pain at Week 16 from Baseline		
n	36	26
Mean (SD)	0.2 (1.96)	0.5 (2.32)
Median	0.0	0.0
Q1, Q3	-1.0, 2.0	0.0, 1.0
Min, Max	-4.0, 4.0	-6.0, 6.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7315: Analysis of MPN-SAF Mean Questionnaire Item #15 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	47	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.04 [0.33] (-0.70, 0.62)	0.77 [0.39] (0.00, 1.54)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.81 [0.51] (-1.82, 0.20)		
MMRM: P-value	0.11		
Corrected Hedges' g (95% CI)	-0.404 (-0.913, 0.106)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.25		
Percent Change in Bone Pain at Week 16 from Baseline			
n	17	15	
Mean (SD)	-2.5 (93.88)	11.6 (67.14)	
Median	-33.3	0.0	
Q1, Q3	-60.0, 20.0	-33.3, 50.0	
Min, Max	-100.0, 200.0	-100.0, 150.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	24	16	
n [2]	17	15	
MMRM: Least Squares Mean [SE] (95% CI)	-19.10 [19.33] (-58.39, 20.18)	19.23 [22.10] (-25.68, 64.14)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-38.33 [27.57] (-94.36, 17.69)		
MMRM: P-value	0.17		
Corrected Hedges' g (95% CI)	-0.453 (-1.156, 0.250)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.24		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.7315: Analysis of MPN-SAF Mean Questionnaire Item #15 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
MPN0115 - Bone Pain at Week 20			
n	44	29	
Mean (SD)	1.5 (2.05)	3.4 (3.17)	
Median	0.0	3.0	
Q1, Q3	0.0, 3.0	0.0, 6.0	
Min, Max	0.0, 8.0	0.0, 9.0	
Return Rate (%)	67%	74%	
Number of Subjects in Risk	51	32	
Return Rate in Risk (%)	86%	91%	
Change in Bone Pain at Week 20 from Baseline			
n	32	24	
Mean (SD)	0.1 (2.28)	0.9 (2.01)	
Median	0.0	0.0	
Q1, Q3	-1.0, 2.0	0.0, 2.0	
Min, Max	-5.0, 4.0	-2.0, 6.0	
Difference in Change from Baseline at Week 20			
n [1]	47	27	
n [2]	32	24	
MMRM: Least Squares Mean [SE] (95% CI)	0.01 [0.35] (-0.68, 0.70)	1.17 [0.40] (0.38, 1.96)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.16 [0.52] (-2.21, -0.12)		
MMRM: P-value	0.030		
Corrected Hedges' g (95% CI)	-0.587 (-1.127, -0.046)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.041		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7315: Analysis of MPN-SAF Mean Questionnaire Item #15 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in Bone Pain at Week 20 from Baseline			
n	14	14	
Mean (SD)	-15.6 (103.81)	15.2 (53.32)	
Median	-38.9	7.1	
Q1, Q3	-100.0, 0.0	-28.6, 50.0	
Min, Max	-100.0, 200.0	-66.7, 133.3	
Difference in Percent Change from Baseline at Week 20			
n [1]	24	16	
n [2]	14	14	
MMRM: Least Squares Mean [SE] (95% CI)	-22.65 [18.59] (-60.44, 15.13)		20.58 [20.89] (-21.87, 63.02)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-43.23 [26.11] (-96.29, 9.84)		
MMRM: P-value	0.11		
Corrected Hedges' g (95% CI)	-0.567 (-1.323, 0.188)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.030		
MPN0115 - Bone Pain at Week 24			
n	41	29	
Mean (SD)	1.4 (1.74)	3.4 (3.29)	
Median	1.0	3.0	
Q1, Q3	0.0, 3.0	0.0, 6.0	
Min, Max	0.0, 7.0	0.0, 9.0	
Return Rate (%)	62%	74%	
Number of Subjects in Risk	48	31	
Return Rate in Risk (%)	85%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7315: Analysis of MPN-SAF Mean Questionnaire Item #15 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Bone Pain at Week 24 from Baseline			
n	27	23	
Mean (SD)	0.0 (2.12)	0.5 (2.31)	
Median	0.0	0.0	
Q1, Q3	0.0, 2.0	0.0, 2.0	
Min, Max	-6.0, 3.0	-3.0, 6.0	
Difference in Change from Baseline at Week 24			
n [1]	47	27	
n [2]	27	23	
MMRM: Least Squares Mean [SE] (95% CI)	-0.04 [0.35] (-0.74, 0.66)		0.78 [0.40] (-0.02, 1.57)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.81 [0.53] (-1.86, 0.24)		
MMRM: P-value	0.13		
Corrected Hedges' g (95% CI)	-0.429 (-0.992, 0.133)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.079		
Percent Change in Bone Pain at Week 24 from Baseline			
n	11	14	
Mean (SD)	-0.8 (106.27)	15.3 (75.62)	
Median	-22.2	0.0	
Q1, Q3	-80.0, 0.0	-33.3, 50.0	
Min, Max	-100.0, 200.0	-100.0, 200.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7315: Analysis of MPN-SAF Mean Questionnaire Item #15 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	**24**	**16**	
n [2]	**11**	**14**	
MMRM: Least Squares Mean [SE] (95% CI)	**-8.88 [20.05] (-49.62, 31.86)**	**19.48 [21.54] (-24.30, 63.26)**	
MMRM: Least Squares Mean Difference [SE] (95% CI)	**-28.36 [27.74] (-84.74, 28.01)**		
MMRM: P-value	**0.31**		
Corrected Hedges' g (95% CI)	**-0.367 (-1.163, 0.430)**		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	**0.35**		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7316: Analysis of MPN-SAF Mean Questionnaire Item #16 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0116 - Fever at Baseline		
n	50	29
Mean (SD)	0.4 (1.26)	0.6 (2.08)
Median	0.0	0.0
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	0.0, 8.0	0.0, 9.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
MPN0116 - Fever at Week 4		
n	60	31
Mean (SD)	0.4 (1.43)	0.5 (1.39)
Median	0.0	0.0
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	0.0, 8.0	0.0, 7.0
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in Fever at Week 4 from Baseline		
n	45	26
Mean (SD)	0.1 (1.34)	-0.3 (2.26)
Median	0.0	0.0
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	-3.0, 8.0	-9.0, 3.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7316: Analysis of MPN-SAF Mean Questionnaire Item #16 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	47	27	
n [2]	45	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.05 [0.15] (-0.23, 0.34)	-0.22 [0.18] (-0.58, 0.14)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.28 [0.23] (-0.18, 0.74)		
MMRM: P-value	0.24		
Corrected Hedges' g (95% CI)	0.285 (-0.200, 0.770)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.85		
Percent Change in Fever at Week 4 from Baseline			
n	5	2	
Mean (SD)	-52.5 (68.69)	-92.9 (10.10)	
Median	-100.0	-92.9	
Q1, Q3	-100.0, -12.5	-100.0, -85.7	
Min, Max	-100.0, 50.0	-100.0, -85.7	
Difference in Percent Change from Baseline at Week 4			
n [1]	5	2	
n [2]	5	2	
MMRM: Least Squares Mean [SE] (95% CI)	-71.25 [18.99] (-111.14, -31.36)	-126.62 [30.81] (-191.36, -61.89)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	55.38 [38.11] (-24.69, 135.44)		
MMRM: P-value	0.16		
Corrected Hedges' g (95% CI)	1.093 (-0.644, 2.829)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.37		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7316: Analysis of MPN-SAF Mean Questionnaire Item #16 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
MPN0116 - Fever at Week 8			
n	57	27	
Mean (SD)	0.4 (1.34)	0.2 (0.51)	
Median	0.0	0.0	
Q1, Q3	0.0, 0.0	0.0, 0.0	
Min, Max	0.0, 7.0	0.0, 2.0	
Return Rate (%)	86%	69%	
Number of Subjects in Risk	61	36	
Return Rate in Risk (%)	93%	75%	
Change in Fever at Week 8 from Baseline			
n	44	24	
Mean (SD)	0.2 (2.01)	-0.4 (2.10)	
Median	0.0	0.0	
Q1, Q3	0.0, 0.0	0.0, 0.0	
Min, Max	-8.0, 7.0	-8.0, 2.0	
Difference in Change from Baseline at Week 8			
n [1]	47	27	
n [2]	44	24	
MMRM: Least Squares Mean [SE] (95% CI)	0.15 [0.15] (-0.14, 0.44)	-0.24 [0.19] (-0.61, 0.13)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.39 [0.24] (-0.08, 0.86)		
MMRM: P-value	0.11		
Corrected Hedges' g (95% CI)	0.399 (-0.103, 0.900)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.57		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7316: Analysis of MPN-SAF Mean Questionnaire Item #16 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Fever at Week 8 from Baseline		
n	5	2
Mean (SD)	-50.0 (70.71)	-87.3 (2.24)
Median	-100.0	-87.3
Q1, Q3	-100.0, 0.0	-88.9, -85.7
Min, Max	-100.0, 50.0	-88.9, -85.7
Difference in Percent Change from Baseline at Week 8		
n [1]	5	2
n [2]	5	2
MMRM: Least Squares Mean [SE] (95% CI)	-68.75 [18.99] (-108.64, -28.86)	-121.07 [30.81] (-185.80, -56.34)
MMRM: Least Squares Mean Difference [SE] (95% CI)	52.32 [38.11] (-27.74, 132.38)	
MMRM: P-value	0.19	
Corrected Hedges' g (95% CI)	1.032 (-0.694, 2.759)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.56	
MPN0116 - Fever at Week 12		
n	51	30
Mean (SD)	0.2 (0.81)	0.2 (0.68)
Median	0.0	0.0
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	0.0, 4.0	0.0, 3.0
Return Rate (%)	77%	77%
Number of Subjects in Risk	59	33
Return Rate in Risk (%)	86%	91%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7316: Analysis of MPN-SAF Mean Questionnaire Item #16 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Fever at Week 12 from Baseline			
n	37	26	
Mean (SD)	-0.1 (1.19)	-0.3 (1.72)	
Median	0.0	0.0	
Q1, Q3	0.0, 0.0	0.0, 0.0	
Min, Max	-5.0, 4.0	-6.0, 2.0	
Difference in Change from Baseline at Week 12			
n [1]	47	27	
n [2]	37	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.06 [0.16] (-0.37, 0.25)		-0.21 [0.18] (-0.57, 0.15)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.15 [0.24] (-0.32, 0.63)		
MMRM: P-value	0.53		
Corrected Hedges' g (95% CI)	0.159 (-0.343, 0.661)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.53		
Percent Change in Fever at Week 12 from Baseline			
n	3	2	
Mean (SD)	-37.5 (78.06)	-76.2 (13.47)	
Median	-62.5	-76.2	
Q1, Q3	-100.0, 50.0	-85.7, -66.7	
Min, Max	-100.0, 50.0	-85.7, -66.7	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7316: Analysis of MPN-SAF Mean Questionnaire Item #16 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 12		
n [1]	5	2
n [2]	3	2
MMRM: Least Squares Mean [SE] (95% CI)	-56.98 [21.47] (-102.08, -11.87)	-109.96 [30.81] (-174.69, -45.23)
MMRM: Least Squares Mean Difference [SE] (95% CI)	52.98 [38.80] (-28.54, 134.50)	
MMRM: P-value	0.19	
Corrected Hedges' g (95% CI)	0.977 (-0.912, 2.866)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.12	
MPN0116 - Fever at Week 16		
n	48	30
Mean (SD)	0.2 (0.91)	0.2 (0.55)
Median	0.0	0.0
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	0.0, 6.0	0.0, 2.0
Return Rate (%)	73%	77%
Number of Subjects in Risk	56	33
Return Rate in Risk (%)	86%	91%
Change in Fever at Week 16 from Baseline		
n	36	26
Mean (SD)	-0.1 (0.64)	-0.4 (1.90)
Median	0.0	0.0
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	-3.0, 1.0	-8.0, 2.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7316: Analysis of MPN-SAF Mean Questionnaire Item #16 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	47	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.12 [0.16] (-0.44, 0.19)	-0.26 [0.18] (-0.62, 0.10)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.13 [0.24] (-0.35, 0.61)		
MMRM: P-value	0.59		
Corrected Hedges' g (95% CI)	0.137 (-0.368, 0.642)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.86		
Percent Change in Fever at Week 16 from Baseline			
n	4	2	
Mean (SD)	-56.3 (51.54)	-80.2 (12.35)	
Median	-62.5	-80.2	
Q1, Q3	-100.0, -12.5	-88.9, -71.4	
Min, Max	-100.0, 0.0	-88.9, -71.4	
Difference in Percent Change from Baseline at Week 16			
n [1]	5	2	
n [2]	4	2	
MMRM: Least Squares Mean [SE] (95% CI)	-62.41 [19.69] (-103.78, -21.05)	-113.93 [30.81] (-178.66, -49.19)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	51.51 [38.26] (-28.86, 131.89)		
MMRM: P-value	0.19		
Corrected Hedges' g (95% CI)	1.018 (-0.774, 2.811)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.12		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7316: Analysis of MPN-SAF Mean Questionnaire Item #16 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
MPN0116 - Fever at Week 20			
n	44	29	
Mean (SD)	0.2 (0.67)	0.2 (0.56)	
Median	0.0	0.0	
Q1, Q3	0.0, 0.0	0.0, 0.0	
Min, Max	0.0, 3.0	0.0, 2.0	
Return Rate (%)	67%	74%	
Number of Subjects in Risk	51	32	
Return Rate in Risk (%)	86%	91%	
Change in Fever at Week 20 from Baseline			
n	32	24	
Mean (SD)	0.1 (0.86)	-0.4 (1.77)	
Median	0.0	0.0	
Q1, Q3	0.0, 0.0	0.0, 0.0	
Min, Max	-3.0, 2.0	-7.0, 1.0	
Difference in Change from Baseline at Week 20			
n [1]	47	27	
n [2]	32	24	
MMRM: Least Squares Mean [SE] (95% CI)	-0.02 [0.17] (-0.35, 0.32)	-0.26 [0.19] (-0.63, 0.11)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.25 [0.26] (-0.26, 0.75)		
MMRM: P-value	0.34		
Corrected Hedges' g (95% CI)	0.254 (-0.277, 0.786)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.57		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7316: Analysis of MPN-SAF Mean Questionnaire Item #16 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Fever at Week 20 from Baseline		
n	3	2
Mean (SD)	-50.0 (86.60)	-74.6 (4.49)
Median	-100.0	-74.6
Q1, Q3	-100.0, 50.0	-77.8, -71.4
Min, Max	-100.0, 50.0	-77.8, -71.4
Difference in Percent Change from Baseline at Week 20		
n [1]	5	2
n [2]	3	2
MMRM: Least Squares Mean [SE] (95% CI)	-46.41 [23.02] (-94.77, 1.94)	-108.37 [30.81] (-173.10, -43.64)
MMRM: Least Squares Mean Difference [SE] (95% CI)	61.96 [41.45] (-25.12, 149.03)	
MMRM: P-value	0.15	
Corrected Hedges' g (95% CI)	1.095 (-0.818, 3.009)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.22	
MPN0116 - Fever at Week 24		
n	41	29
Mean (SD)	0.2 (0.57)	0.2 (0.64)
Median	0.0	0.0
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	0.0, 2.0	0.0, 3.0
Return Rate (%)	62%	74%
Number of Subjects in Risk	48	31
Return Rate in Risk (%)	85%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7316: Analysis of MPN-SAF Mean Questionnaire Item #16 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Fever at Week 24 from Baseline			
n	27	23	
Mean (SD)	0.1 (0.87)	-0.4 (1.78)	
Median	0.0	0.0	
Q1, Q3	0.0, 0.0	0.0, 0.0	
Min, Max	-3.0, 2.0	-6.0, 1.0	
Difference in Change from Baseline at Week 24			
n [1]	47	27	
n [2]	27	23	
MMRM: Least Squares Mean [SE] (95% CI)	-0.04 [0.19] (-0.40, 0.33)	-0.26 [0.19] (-0.64, 0.13)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.22 [0.27] (-0.31, 0.75)		
MMRM: P-value	0.41		
Corrected Hedges' g (95% CI)	0.227 (-0.331, 0.785)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.27		
Percent Change in Fever at Week 24 from Baseline			
n	3	2	
Mean (SD)	-66.7 (57.74)	-76.2 (13.47)	
Median	-100.0	-76.2	
Q1, Q3	-100.0, 0.0	-85.7, -66.7	
Min, Max	-100.0, 0.0	-85.7, -66.7	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7316: Analysis of MPN-SAF Mean Questionnaire Item #16 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	5	2	
n [2]	3	2	
MMRM: Least Squares Mean [SE] (95% CI)	-63.37 [24.01] (-113.81, -12.93)	-109.96 [30.81] (-174.69, -45.23)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	46.59 [42.59] (-42.89, 136.06)		
MMRM: P-value	0.29		
Corrected Hedges' g (95% CI)	0.802 (-1.055, 2.659)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.22		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

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Table 2.7317: Analysis of MPN-SAF Mean Questionnaire Item #17 Score and Change from Baseline

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0117 - Weight Loss in 6 Months at Baseline		
n	50	29
Mean (SD)	1.9 (2.83)	1.4 (2.59)
Median	0.0	0.0
Q1, Q3	0.0, 3.0	0.0, 1.0
Min, Max	0.0, 10.0	0.0, 8.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
MPN0117 - Weight Loss in 6 Months at Week 4		
n	60	31
Mean (SD)	1.6 (2.89)	1.9 (3.18)
Median	0.0	0.0
Q1, Q3	0.0, 2.0	0.0, 3.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in Weight Loss in 6 Months at Week 4 from Baseline		
n	45	26
Mean (SD)	-0.1 (2.75)	0.2 (2.02)
Median	0.0	0.0
Q1, Q3	-1.0, 0.0	0.0, 0.0
Min, Max	-6.0, 9.0	-4.0, 7.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7317: Analysis of MPN-SAF Mean Questionnaire Item #17 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	47	27	
n [2]	45	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.14 [0.38] (-0.89, 0.61)	0.02 [0.46] (-0.91, 0.95)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.16 [0.60] (-1.35, 1.04)		
MMRM: P-value	0.80		
Corrected Hedges' g (95% CI)	-0.062 (-0.545, 0.421)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.32		
Percent Change in Weight Loss in 6 Months at Week 4 from Baseline			
n	20	9	
Mean (SD)	-20.7 (135.63)	-19.6 (66.72)	
Median	-46.4	-14.3	
Q1, Q3	-100.0, -7.1	-60.0, 12.5	
Min, Max	-100.0, 500.0	-100.0, 100.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	21	9	
n [2]	20	9	
MMRM: Least Squares Mean [SE] (95% CI)	-25.68 [27.98] (-83.42, 32.07)	-20.07 [41.91] (-106.57, 66.44)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-5.61 [50.56] (-109.96, 98.74)		
MMRM: P-value	0.91		
Corrected Hedges' g (95% CI)	-0.044 (-0.830, 0.743)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.47		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7317: Analysis of MPN-SAF Mean Questionnaire Item #17 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
MPN0117 - Weight Loss in 6 Months at Week 8			
n	57	27	
Mean (SD)	1.6 (2.50)	0.6 (1.34)	
Median	0.0	0.0	
Q1, Q3	0.0, 2.0	0.0, 0.0	
Min, Max	0.0, 9.0	0.0, 5.0	
Return Rate (%)	86%	69%	
Number of Subjects in Risk	61	36	
Return Rate in Risk (%)	93%	75%	
Change in Weight Loss in 6 Months at Week 8 from Baseline			
n	44	24	
Mean (SD)	0.0 (2.93)	-1.0 (2.46)	
Median	0.0	0.0	
Q1, Q3	0.0, 1.0	-0.5, 0.0	
Min, Max	-10.0, 9.0	-7.0, 2.0	
Difference in Change from Baseline at Week 8			
n [1]	47	27	
n [2]	44	24	
MMRM: Least Squares Mean [SE] (95% CI)		0.16 [0.34] (-0.52, 0.84)	-1.19 [0.42] (-2.02, -0.35)
MMRM: Least Squares Mean Difference [SE] (95% CI)		1.34 [0.54] (0.27, 2.41)	
MMRM: P-value		0.015	
Corrected Hedges' g (95% CI)		0.606 (0.098, 1.113)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value		0.14	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7317: Analysis of MPN-SAF Mean Questionnaire Item #17 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in Weight Loss in 6 Months at Week 8 from Baseline			
n	21	8	
Mean (SD)	2.2 (80.26)	-32.2 (102.48)	
Median	0.0	-68.8	
Q1, Q3	-50.0, 25.0	-100.0, -10.0	
Min, Max	-100.0, 200.0	-100.0, 200.0	
Difference in Percent Change from Baseline at Week 8			
n [1]	21	9	
n [2]	21	8	
MMRM: Least Squares Mean [SE] (95% CI)		4.99 [17.87] (-31.90, 41.88)	-33.28 [27.24] (-89.51, 22.95)
MMRM: Least Squares Mean Difference [SE] (95% CI)		38.26 [32.49] (-28.78, 105.31)	
MMRM: P-value		0.25	
Corrected Hedges' g (95% CI)		0.461 (-0.362, 1.284)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value		0.26	
MPN0117 - Weight Loss in 6 Months at Week 12			
n	51	30	
Mean (SD)	1.5 (2.28)	1.4 (2.70)	
Median	0.0	0.0	
Q1, Q3	0.0, 3.0	0.0, 1.0	
Min, Max	0.0, 8.0	0.0, 10.0	
Return Rate (%)	77%	77%	
Number of Subjects in Risk	59	33	
Return Rate in Risk (%)	86%	91%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7317: Analysis of MPN-SAF Mean Questionnaire Item #17 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Weight Loss in 6 Months at Week 12 from Baseline			
n	37	26	
Mean (SD)	-0.2 (2.28)	0.0 (2.22)	
Median	0.0	0.0	
Q1, Q3	0.0, 1.0	0.0, 1.0	
Min, Max	-7.0, 4.0	-7.0, 7.0	
Difference in Change from Baseline at Week 12			
n [1]	47	27	
n [2]	37	26	
MMRM: Least Squares Mean [SE] (95% CI)		-0.03 [0.39] (-0.81, 0.74)	0.00 [0.46] (-0.92, 0.93)
MMRM: Least Squares Mean Difference [SE] (95% CI)		-0.04 [0.60] (-1.24, 1.17)	
MMRM: P-value		0.95	
Corrected Hedges' g (95% CI)		-0.015 (-0.517, 0.487)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value		0.38	
Percent Change in Weight Loss in 6 Months at Week 12 from Baseline			
n	18	9	
Mean (SD)	15.0 (120.50)	-23.9 (68.46)	
Median	-5.6	-14.3	
Q1, Q3	-100.0, 100.0	-100.0, 14.3	
Min, Max	-100.0, 300.0	-100.0, 100.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7317: Analysis of MPN-SAF Mean Questionnaire Item #17 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 12		
n [1]	21	9
n [2]	18	9
MMRM: Least Squares Mean [SE] (95% CI)	7.03 [23.72] (-41.93, 55.99)	-24.39 [34.95] (-96.54, 47.75)
MMRM: Least Squares Mean Difference [SE] (95% CI)	31.42 [42.36] (-56.01, 118.86)	
MMRM: P-value	0.47	
Corrected Hedges' g (95% CI)	0.299 (-0.505, 1.103)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.96	
MPN0117 - Weight Loss in 6 Months at Week 16		
n	48	30
Mean (SD)	1.2 (1.77)	1.1 (2.25)
Median	0.0	0.0
Q1, Q3	0.0, 2.0	0.0, 1.0
Min, Max	0.0, 7.0	0.0, 9.0
Return Rate (%)	73%	77%
Number of Subjects in Risk	56	33
Return Rate in Risk (%)	86%	91%
Change in Weight Loss in 6 Months at Week 16 from Baseline		
n	36	26
Mean (SD)	-0.6 (3.18)	-0.3 (2.10)
Median	0.0	0.0
Q1, Q3	-1.0, 0.5	0.0, 0.0
Min, Max	-10.0, 6.0	-7.0, 3.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7317: Analysis of MPN-SAF Mean Questionnaire Item #17 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	47	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.23 [0.34] (-0.91, 0.45)	-0.45 [0.38] (-1.21, 0.30)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.23 [0.51] (-0.78, 1.24)		
MMRM: P-value	0.66		
Corrected Hedges' g (95% CI)	0.112 (-0.393, 0.617)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.25		
Percent Change in Weight Loss in 6 Months at Week 16 from Baseline			
n	16	9	
Mean (SD)	19.9 (181.57)	-7.7 (104.75)	
Median	-33.3	-12.5	
Q1, Q3	-100.0, 12.5	-100.0, 28.6	
Min, Max	-100.0, 600.0	-100.0, 200.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	21	9	
n [2]	16	9	
MMRM: Least Squares Mean [SE] (95% CI)	31.78 [34.87] (-40.20, 103.75)	-8.24 [49.59] (-110.59, 94.11)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	40.02 [60.74] (-85.35, 165.39)		
MMRM: P-value	0.52		
Corrected Hedges' g (95% CI)	0.271 (-0.549, 1.091)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.47		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.7317: Analysis of MPN-SAF Mean Questionnaire Item #17 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0117 - Weight Loss in 6 Months at Week 20		
n	44	29
Mean (SD)	1.6 (2.44)	1.6 (3.02)
Median	0.0	0.0
Q1, Q3	0.0, 3.0	0.0, 1.0
Min, Max	0.0, 8.0	0.0, 10.0
Return Rate (%)	67%	74%
Number of Subjects in Risk	51	32
Return Rate in Risk (%)	86%	91%
Change in Weight Loss in 6 Months at Week 20 from Baseline		
n	32	24
Mean (SD)	0.2 (2.27)	0.2 (2.23)
Median	0.0	0.0
Q1, Q3	0.0, 1.0	0.0, 0.0
Min, Max	-6.0, 6.0	-6.0, 6.0
Difference in Change from Baseline at Week 20		
n [1]	47	27
n [2]	32	24
MMRM: Least Squares Mean [SE] (95% CI)	0.50 [0.41] (-0.31, 1.31)	0.01 [0.47] (-0.94, 0.96)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.49 [0.62] (-0.75, 1.74)	
MMRM: P-value	0.43	
Corrected Hedges' g (95% CI)	0.211 (-0.320, 0.742)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.56	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn17-rt.pdf 24AUG2023:17:01

Table 2.7317: Analysis of MPN-SAF Mean Questionnaire Item #17 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Weight Loss in 6 Months at Week 20 from Baseline		
n	11	8
Mean (SD)	14.5 (200.20)	47.1 (230.47)
Median	-30.0	0.0
Q1, Q3	-100.0, 14.3	-92.9, 31.4
Min, Max	-100.0, 600.0	-100.0, 600.0
Difference in Percent Change from Baseline at Week 20		
n [1]	21	9
n [2]	11	8
MMRM: Least Squares Mean [SE] (95% CI)	46.60 [55.62] (-68.19, 161.40)	25.61 [81.42] (-142.43, 193.64)
MMRM: Least Squares Mean Difference [SE] (95% CI)	21.00 [98.80] (-182.92, 224.92)	
MMRM: P-value	0.83	
Corrected Hedges' g (95% CI)	0.098 (-0.813, 1.009)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.44	
MPN0117 - Weight Loss in 6 Months at Week 24		
n	41	29
Mean (SD)	1.1 (1.69)	1.5 (2.65)
Median	0.0	0.0
Q1, Q3	0.0, 2.0	0.0, 1.0
Min, Max	0.0, 5.0	0.0, 8.0
Return Rate (%)	62%	74%
Number of Subjects in Risk	48	31
Return Rate in Risk (%)	85%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7317: Analysis of MPN-SAF Mean Questionnaire Item #17 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Weight Loss in 6 Months at Week 24 from Baseline			
n	27	23	
Mean (SD)	-0.4 (3.06)	0.2 (1.78)	
Median	0.0	0.0	
Q1, Q3	-2.0, 0.0	0.0, 0.0	
Min, Max	-10.0, 5.0	-2.0, 8.0	
Difference in Change from Baseline at Week 24			
n [1]	47	27	
n [2]	27	23	
MMRM: Least Squares Mean [SE] (95% CI)		-0.05 [0.38] (-0.82, 0.71)	0.04 [0.42] (-0.81, 0.88)
MMRM: Least Squares Mean Difference [SE] (95% CI)		-0.09 [0.57] (-1.23, 1.05)	
MMRM: P-value	0.88		
Corrected Hedges' g (95% CI)	-0.043 (-0.600, 0.513)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.13		
Percent Change in Weight Loss in 6 Months at Week 24 from Baseline			
n	9	7	
Mean (SD)	-26.0 (125.43)	-9.2 (60.71)	
Median	-55.6	0.0	
Q1, Q3	-100.0, -33.3	-50.0, 0.0	
Min, Max	-100.0, 300.0	-100.0, 100.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7317: Analysis of MPN-SAF Mean Questionnaire Item #17 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	21	9	
n [2]	9	7	
MMRM: Least Squares Mean [SE] (95% CI)	2.36 [27.79] (-55.00, 59.72)	-10.23 [40.21] (-93.22, 72.75)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	12.59 [49.11] (-88.76, 113.94)		
MMRM: P-value	0.80		
Corrected Hedges' g (95% CI)	0.127 (-0.862, 1.115)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.049		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7318: Analysis of MPN-SAF Mean Questionnaire Item #18 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0118 - Overall Quality of Life at Baseline		
n	50	29
Mean (SD)	4.0 (2.56)	5.2 (2.20)
Median	4.5	5.0
Q1, Q3	2.0, 6.0	4.0, 6.0
Min, Max	0.0, 9.0	1.0, 10.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
MPN0118 - Overall Quality of Life at Week 4		
n	60	31
Mean (SD)	4.1 (2.15)	4.9 (2.39)
Median	4.0	5.0
Q1, Q3	3.0, 5.0	3.0, 7.0
Min, Max	0.0, 8.0	0.0, 10.0
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in Overall Quality of Life at Week 4 from Baseline		
n	45	26
Mean (SD)	0.0 (1.91)	-0.2 (2.61)
Median	0.0	0.0
Q1, Q3	-1.0, 1.0	-1.0, 2.0
Min, Max	-6.0, 5.0	-8.0, 4.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7318: Analysis of MPN-SAF Mean Questionnaire Item #18 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	47	27	
n [2]	45	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.07 [0.30] (-0.52, 0.67)		0.03 [0.36] (-0.69, 0.75)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.04 [0.47] (-0.90, 0.98)		
MMRM: P-value	0.93		
Corrected Hedges' g (95% CI)	0.022 (-0.461, 0.505)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.64		
Percent Change in Overall Quality of Life at Week 4 from Baseline			
n	40	26	
Mean (SD)	15.0 (91.07)	6.6 (62.24)	
Median	0.0	0.0	
Q1, Q3	-28.6, 29.2	-20.0, 33.3	
Min, Max	-100.0, 500.0	-100.0, 150.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	41	27	
n [2]	40	26	
MMRM: Least Squares Mean [SE] (95% CI)	21.71 [11.90] (-2.09, 45.50)		9.47 [13.76] (-18.04, 36.98)
MMRM: Least Squares Mean Difference [SE] (95% CI)	12.24 [18.18] (-24.10, 48.58)		
MMRM: P-value	0.50		
Corrected Hedges' g (95% CI)	0.165 (-0.330, 0.659)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.90		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7318: Analysis of MPN-SAF Mean Questionnaire Item #18 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0118 - Overall Quality of Life at Week 8		
n	57	27
Mean (SD)	4.4 (2.47)	4.6 (2.10)
Median	5.0	5.0
Q1, Q3	3.0, 6.0	3.0, 6.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	86%	69%
Number of Subjects in Risk	61	36
Return Rate in Risk (%)	93%	75%
Change in Overall Quality of Life at Week 8 from Baseline		
n	44	24
Mean (SD)	0.3 (1.54)	-0.6 (2.76)
Median	0.0	0.0
Q1, Q3	-1.0, 1.0	-2.0, 1.0
Min, Max	-2.0, 5.0	-8.0, 4.0
Difference in Change from Baseline at Week 8		
n [1]	47	27
n [2]	44	24
MMRM: Least Squares Mean [SE] (95% CI)	0.30 [0.30] (-0.31, 0.90)	-0.13 [0.37] (-0.88, 0.61)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.43 [0.48] (-0.53, 1.39)	
MMRM: P-value	0.37	
Corrected Hedges' g (95% CI)	0.219 (-0.280, 0.718)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.11	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7318: Analysis of MPN-SAF Mean Questionnaire Item #18 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Overall Quality of Life at Week 8 from Baseline		
n	38	24
Mean (SD)	13.1 (63.27)	15.5 (101.08)
Median	0.0	0.0
Q1, Q3	-14.3, 33.3	-33.3, 26.7
Min, Max	-100.0, 300.0	-100.0, 400.0
Difference in Percent Change from Baseline at Week 8		
n [1]	41	27
n [2]	38	24
MMRM: Least Squares Mean [SE] (95% CI)	23.82 [11.84] (0.15, 47.48)	21.11 [13.85] (-6.58, 48.80)
MMRM: Least Squares Mean Difference [SE] (95% CI)	2.71 [18.12] (-33.51, 38.92)	
MMRM: P-value	0.88	
Corrected Hedges' g (95% CI)	0.038 (-0.473, 0.549)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.19	
MPN0118 - Overall Quality of Life at Week 12		
n	51	30
Mean (SD)	3.8 (2.31)	4.7 (2.07)
Median	4.0	5.0
Q1, Q3	2.0, 5.0	3.0, 6.0
Min, Max	0.0, 8.0	1.0, 10.0
Return Rate (%)	77%	77%
Number of Subjects in Risk	59	33
Return Rate in Risk (%)	86%	91%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7318: Analysis of MPN-SAF Mean Questionnaire Item #18 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Overall Quality of Life at Week 12 from Baseline			
n	37	26	
Mean (SD)	0.0 (2.57)	-0.5 (2.39)	
Median	0.0	0.0	
Q1, Q3	-1.0, 1.0	-2.0, 1.0	
Min, Max	-6.0, 7.0	-5.0, 4.0	
Difference in Change from Baseline at Week 12			
n [1]	47	27	
n [2]	37	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.11 [0.36] (-0.83, 0.61)	-0.01 [0.41] (-0.83, 0.81)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.10 [0.55] (-1.20, 1.00)		
MMRM: P-value	0.86		
Corrected Hedges' g (95% CI)	-0.046 (-0.547, 0.456)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.61		
Percent Change in Overall Quality of Life at Week 12 from Baseline			
n	32	26	
Mean (SD)	18.5 (135.76)	16.4 (96.88)	
Median	0.0	0.0	
Q1, Q3	-31.0, 22.5	-33.3, 25.0	
Min, Max	-100.0, 700.0	-80.0, 400.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7318: Analysis of MPN-SAF Mean Questionnaire Item #18 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 12			
n [1]	41	27	
n [2]	32	26	
MMRM: Least Squares Mean [SE] (95% CI)	25.31 [19.07] (-12.82, 63.43)		24.00 [21.38] (-18.73, 66.73)
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.31 [28.62] (-55.90, 58.51)		
MMRM: P-value	0.96		
Corrected Hedges' g (95% CI)	0.012 (-0.506, 0.529)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.67		
MPN0118 - Overall Quality of Life at Week 16			
n	48	30	
Mean (SD)	3.9 (2.27)	5.0 (2.51)	
Median	4.0	5.0	
Q1, Q3	2.0, 5.0	4.0, 7.0	
Min, Max	0.0, 8.0	0.0, 10.0	
Return Rate (%)	73%	77%	
Number of Subjects in Risk	56	33	
Return Rate in Risk (%)	86%	91%	
Change in Overall Quality of Life at Week 16 from Baseline			
n	36	26	
Mean (SD)	-0.1 (2.16)	-0.1 (2.33)	
Median	0.0	-0.5	
Q1, Q3	-2.0, 1.5	-2.0, 2.0	
Min, Max	-6.0, 4.0	-5.0, 4.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7318: Analysis of MPN-SAF Mean Questionnaire Item #18 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	47	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.13 [0.37] (-0.60, 0.86)	0.37 [0.42] (-0.46, 1.20)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.24 [0.55] (-1.35, 0.86)		
MMRM: P-value	0.66		
Corrected Hedges' g (95% CI)	-0.110 (-0.615, 0.394)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.96		
Percent Change in Overall Quality of Life at Week 16 from Baseline			
n	32	26	
Mean (SD)	17.7 (92.71)	15.1 (96.47)	
Median	0.0	-5.0	
Q1, Q3	-31.0, 32.5	-28.6, 33.3	
Min, Max	-100.0, 400.0	-100.0, 400.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	41	27	
n [2]	32	26	
MMRM: Least Squares Mean [SE] (95% CI)	29.46 [14.60] (0.28, 58.64)	22.36 [16.41] (-10.44, 55.17)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	7.09 [21.91] (-36.71, 50.90)		
MMRM: P-value	0.75		
Corrected Hedges' g (95% CI)	0.084 (-0.433, 0.602)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.99		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.7318: Analysis of MPN-SAF Mean Questionnaire Item #18 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPN0118 - Overall Quality of Life at Week 20		
n	44	29
Mean (SD)	3.7 (2.31)	4.9 (2.94)
Median	4.0	5.0
Q1, Q3	2.0, 5.5	3.0, 6.0
Min, Max	0.0, 8.0	0.0, 10.0
Return Rate (%)	67%	74%
Number of Subjects in Risk	51	32
Return Rate in Risk (%)	86%	91%
Change in Overall Quality of Life at Week 20 from Baseline		
n	32	24
Mean (SD)	0.1 (2.27)	-0.3 (2.46)
Median	0.0	-0.5
Q1, Q3	-1.0, 1.0	-2.0, 1.0
Min, Max	-6.0, 5.0	-6.0, 4.0
Difference in Change from Baseline at Week 20		
n [1]	47	27
n [2]	32	24
MMRM: Least Squares Mean [SE] (95% CI)	-0.01 [0.39] (-0.78, 0.77)	0.35 [0.45] (-0.54, 1.24)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.36 [0.59] (-1.54, 0.82)	
MMRM: P-value	0.55	
Corrected Hedges' g (95% CI)	-0.160 (-0.690, 0.370)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.49	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7318: Analysis of MPN-SAF Mean Questionnaire Item #18 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in Overall Quality of Life at Week 20 from Baseline			
n	28	24	
Mean (SD)	11.8 (62.25)	8.3 (96.70)	
Median	0.0	-8.3	
Q1, Q3	-28.6, 32.5	-29.2, 18.3	
Min, Max	-100.0, 166.7	-100.0, 400.0	
Difference in Percent Change from Baseline at Week 20			
n [1]	41	27	
n [2]	28	24	
MMRM: Least Squares Mean [SE] (95% CI)	12.67 [13.65] (-14.61, 39.95)	18.62 [14.64] (-10.65, 47.90)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-5.95 [19.99] (-45.90, 34.00)		
MMRM: P-value	0.77		
Corrected Hedges' g (95% CI)	-0.081 (-0.627, 0.464)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.74		
MPN0118 - Overall Quality of Life at Week 24			
n	41	29	
Mean (SD)	3.9 (2.32)	5.1 (2.71)	
Median	4.0	5.0	
Q1, Q3	2.0, 5.0	3.0, 7.0	
Min, Max	0.0, 8.0	0.0, 10.0	
Return Rate (%)	62%	74%	
Number of Subjects in Risk	48	31	
Return Rate in Risk (%)	85%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.7318: Analysis of MPN-SAF Mean Questionnaire Item #18 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Overall Quality of Life at Week 24 from Baseline			
n	27	23	
Mean (SD)	0.2 (2.56)	-0.3 (2.30)	
Median	0.0	0.0	
Q1, Q3	-1.0, 1.0	-2.0, 1.0	
Min, Max	-6.0, 8.0	-5.0, 3.0	
Difference in Change from Baseline at Week 24			
n [1]	47	27	
n [2]	27	23	
MMRM: Least Squares Mean [SE] (95% CI)	0.16 [0.42] (-0.67, 0.99)	0.58 [0.47] (-0.35, 1.52)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.42 [0.63] (-1.68, 0.83)		
MMRM: P-value	0.50		
Corrected Hedges' g (95% CI)	-0.189 (-0.747, 0.368)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.47		
Percent Change in Overall Quality of Life at Week 24 from Baseline			
n	24	23	
Mean (SD)	10.1 (70.84)	-0.5 (47.40)	
Median	0.0	0.0	
Q1, Q3	-28.6, 29.2	-37.5, 16.7	
Min, Max	-100.0, 200.0	-100.0, 100.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7318: Analysis of MPN-SAF Mean Questionnaire Item #18 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	41	27	
n [2]	24	23	
MMRM: Least Squares Mean [SE] (95% CI)	16.39 [12.25] (-8.09, 40.87)		15.45 [12.97] (-10.48, 41.37)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.94 [17.80] (-34.65, 36.54)		
MMRM: P-value	0.96		
Corrected Hedges' g (95% CI)	0.015 (-0.557, 0.587)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.51		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

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Table 2.7319: Analysis of MPN-SAF Mean Questionnaire Item #19 Score and Change from Baseline

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
BFI0101 - Fatigue Right Now at Baseline		
n	50	29
Mean (SD)	3.8 (3.01)	4.9 (2.98)
Median	3.0	6.0
Q1, Q3	1.0, 6.0	3.0, 7.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
BFI0101 - Fatigue Right Now at Week 4		
n	60	31
Mean (SD)	3.7 (2.66)	5.0 (2.76)
Median	3.0	5.0
Q1, Q3	1.5, 6.0	3.0, 8.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in Fatigue Right Now at Week 4 from Baseline		
n	45	26
Mean (SD)	0.1 (2.52)	0.3 (2.82)
Median	0.0	0.0
Q1, Q3	-1.0, 2.0	-2.0, 1.0
Min, Max	-6.0, 7.0	-5.0, 8.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7319: Analysis of MPN-SAF Mean Questionnaire Item #19 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	47	27	
n [2]	45	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.15 [0.36] (-0.87, 0.57)		0.59 [0.44] (-0.29, 1.47)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.74 [0.57] (-1.88, 0.40)		
MMRM: P-value	0.20		
Corrected Hedges' g (95% CI)	-0.310 (-0.796, 0.175)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.84		
Percent Change in Fatigue Right Now at Week 4 from Baseline			
n	41	21	
Mean (SD)	25.6 (109.10)	-9.7 (51.28)	
Median	0.0	0.0	
Q1, Q3	-50.0, 50.0	-40.0, 14.3	
Min, Max	-100.0, 350.0	-100.0, 133.3	
Difference in Percent Change from Baseline at Week 4			
n [1]	42	22	
n [2]	41	21	
MMRM: Least Squares Mean [SE] (95% CI)	23.65 [16.74] (-9.85, 57.16)		8.13 [20.04] (-31.98, 48.24)
MMRM: Least Squares Mean Difference [SE] (95% CI)	15.52 [26.04] (-36.60, 67.65)		
MMRM: P-value	0.55		
Corrected Hedges' g (95% CI)	0.150 (-0.377, 0.676)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.56		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.7319: Analysis of MPN-SAF Mean Questionnaire Item #19 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
BFI0101 - Fatigue Right Now at Week 8			
n	57	27	
Mean (SD)	3.7 (2.65)	5.2 (2.49)	
Median	3.0	5.0	
Q1, Q3	2.0, 5.0	3.0, 7.0	
Min, Max	0.0, 9.0	0.0, 10.0	
Return Rate (%)	86%	69%	
Number of Subjects in Risk	61	36	
Return Rate in Risk (%)	93%	75%	
Change in Fatigue Right Now at Week 8 from Baseline			
n	44	24	
Mean (SD)	0.4 (2.74)	0.3 (2.69)	
Median	0.0	0.0	
Q1, Q3	-1.0, 2.0	-1.5, 2.0	
Min, Max	-7.0, 7.0	-4.0, 7.0	
Difference in Change from Baseline at Week 8			
n [1]	47	27	
n [2]	44	24	
MMRM: Least Squares Mean [SE] (95% CI)	0.22 [0.36] (-0.49, 0.94)	0.79 [0.44] (-0.09, 1.66)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.56 [0.57] (-1.69, 0.56)		
MMRM: P-value	0.32		
Corrected Hedges' g (95% CI)	-0.243 (-0.742, 0.256)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.71		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn19-rt.pdf 24AUG2023:17:01

Table 2.7319: Analysis of MPN-SAF Mean Questionnaire Item #19 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in Fatigue Right Now at Week 8 from Baseline			
n	40	19	
Mean (SD)	61.1 (146.35)	-1.7 (40.39)	
Median	8.3	0.0	
Q1, Q3	-25.0, 100.0	-40.0, 28.6	
Min, Max	-100.0, 600.0	-50.0, 100.0	
Difference in Percent Change from Baseline at Week 8			
n [1]	42	22	
n [2]	40	19	
MMRM: Least Squares Mean [SE] (95% CI)	57.41 [18.98] (19.42, 95.40)	23.20 [24.07] (-24.97, 71.37)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	34.21 [30.58] (-27.00, 95.43)		
MMRM: P-value	0.27		
Corrected Hedges' g (95% CI)	0.292 (-0.256, 0.841)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.31		
BFI0101 - Fatigue Right Now at Week 12			
n	51	30	
Mean (SD)	3.7 (2.66)	5.6 (2.53)	
Median	3.0	5.0	
Q1, Q3	2.0, 6.0	4.0, 8.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	77%	77%	
Number of Subjects in Risk	59	33	
Return Rate in Risk (%)	86%	91%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7319: Analysis of MPN-SAF Mean Questionnaire Item #19 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Fatigue Right Now at Week 12 from Baseline		
n	37	26
Mean (SD)	0.6 (2.36)	0.6 (2.61)
Median	0.0	0.5
Q1, Q3	-1.0, 2.0	-1.0, 2.0
Min, Max	-5.0, 5.0	-4.0, 6.0
Difference in Change from Baseline at Week 12		
n [1]	47	27
n [2]	37	26
MMRM: Least Squares Mean [SE] (95% CI)	0.30 [0.38] (-0.46, 1.05)	1.11 [0.43] (0.26, 1.95)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.81 [0.57] (-1.94, 0.32)	
MMRM: P-value	0.16	
Corrected Hedges' g (95% CI)	-0.356 (-0.862, 0.149)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.90	
Percent Change in Fatigue Right Now at Week 12 from Baseline		
n	33	21
Mean (SD)	76.9 (164.93)	-0.5 (42.12)
Median	0.0	0.0
Q1, Q3	-25.0, 100.0	-22.2, 33.3
Min, Max	-100.0, 500.0	-100.0, 80.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7319: Analysis of MPN-SAF Mean Questionnaire Item #19 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 12			
n [1]	42	22	
n [2]	33	21	
MMRM: Least Squares Mean [SE] (95% CI)	72.20 [21.43] (29.31, 115.10)	23.55 [26.15] (-28.78, 75.89)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	48.65 [33.74] (-18.89, 116.19)		
MMRM: P-value	0.15		
Corrected Hedges' g (95% CI)	0.393 (-0.159, 0.946)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.55		
BFI0101 - Fatigue Right Now at Week 16			
n	48	30	
Mean (SD)	3.0 (2.36)	5.1 (2.81)	
Median	2.0	5.0	
Q1, Q3	1.0, 5.0	4.0, 8.0	
Min, Max	0.0, 9.0	0.0, 10.0	
Return Rate (%)	73%	77%	
Number of Subjects in Risk	56	33	
Return Rate in Risk (%)	86%	91%	
Change in Fatigue Right Now at Week 16 from Baseline			
n	36	26	
Mean (SD)	-0.6 (2.61)	0.5 (2.75)	
Median	0.0	0.0	
Q1, Q3	-1.0, 0.5	-1.0, 3.0	
Min, Max	-9.0, 5.0	-4.0, 6.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7319: Analysis of MPN-SAF Mean Questionnaire Item #19 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	47	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.52 [0.38] (-1.27, 0.23)	0.96 [0.43] (0.11, 1.80)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.48 [0.57] (-2.61, -0.35)		
MMRM: P-value	0.011		
Corrected Hedges' g (95% CI)	-0.657 (-1.174, -0.139)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.27		
Percent Change in Fatigue Right Now at Week 16 from Baseline			
n	32	21	
Mean (SD)	19.5 (119.46)	3.3 (54.69)	
Median	0.0	0.0	
Q1, Q3	-47.2, 33.3	-42.9, 28.6	
Min, Max	-100.0, 500.0	-100.0, 150.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	42	22	
n [2]	32	21	
MMRM: Least Squares Mean [SE] (95% CI)	32.68 [18.79] (-4.93, 70.30)	27.55 [22.41] (-17.30, 72.41)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	5.13 [29.13] (-53.18, 63.44)		
MMRM: P-value	0.86		
Corrected Hedges' g (95% CI)	0.048 (-0.502, 0.599)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.60		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7319: Analysis of MPN-SAF Mean Questionnaire Item #19 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
BFI0101 - Fatigue Right Now at Week 20		
n	44	29
Mean (SD)	3.2 (2.21)	5.2 (2.67)
Median	3.0	4.0
Q1, Q3	2.0, 5.0	4.0, 8.0
Min, Max	0.0, 8.0	0.0, 10.0
Return Rate (%)	67%	74%
Number of Subjects in Risk	51	32
Return Rate in Risk (%)	86%	91%
Change in Fatigue Right Now at Week 20 from Baseline		
n	32	24
Mean (SD)	-0.5 (2.68)	0.1 (2.64)
Median	0.0	0.0
Q1, Q3	-2.0, 1.0	-1.5, 1.0
Min, Max	-7.0, 4.0	-5.0, 5.0
Difference in Change from Baseline at Week 20		
n [1]	47	27
n [2]	32	24
MMRM: Least Squares Mean [SE] (95% CI)	-0.22 [0.37] (-0.96, 0.51)	0.85 [0.42] (0.01, 1.69)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.07 [0.56] (-2.18, 0.04)	
MMRM: P-value	0.058	
Corrected Hedges' g (95% CI)	-0.511 (-1.048, 0.027)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.44	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn19-rt.pdf 24AUG2023:17:01

Table 2.7319: Analysis of MPN-SAF Mean Questionnaire Item #19 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in Fatigue Right Now at Week 20 from Baseline			
n	28	21	
Mean (SD)	17.0 (116.11)	2.1 (44.99)	
Median	-10.0	0.0	
Q1, Q3	-50.0, 50.0	-33.3, 14.3	
Min, Max	-100.0, 400.0	-62.5, 100.0	
Difference in Percent Change from Baseline at Week 20			
n [1]	42	22	
n [2]	28	21	
MMRM: Least Squares Mean [SE] (95% CI)	30.66 [17.86] (-5.09, 66.41)	26.31 [20.47] (-14.66, 67.27)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	4.35 [27.04] (-49.77, 58.48)		
MMRM: P-value	0.87		
Corrected Hedges' g (95% CI)	0.045 (-0.520, 0.611)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.65		
BFI0101 - Fatigue Right Now at Week 24			
n	41	29	
Mean (SD)	3.2 (2.45)	5.6 (3.04)	
Median	2.0	5.0	
Q1, Q3	2.0, 4.0	3.0, 8.0	
Min, Max	0.0, 9.0	0.0, 10.0	
Return Rate (%)	62%	74%	
Number of Subjects in Risk	48	31	
Return Rate in Risk (%)	85%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7319: Analysis of MPN-SAF Mean Questionnaire Item #19 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Fatigue Right Now at Week 24 from Baseline			
n	27	23	
Mean (SD)	0.0 (2.90)	0.4 (2.48)	
Median	0.0	0.0	
Q1, Q3	-2.0, 2.0	-1.0, 2.0	
Min, Max	-7.0, 6.0	-5.0, 5.0	
Difference in Change from Baseline at Week 24			
n [1]	47	27	
n [2]	27	23	
MMRM: Least Squares Mean [SE] (95% CI)	-0.25 [0.41] (-1.06, 0.56)	1.28 [0.44] (0.41, 2.15)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.53 [0.60] (-2.72, -0.35)		
MMRM: P-value	0.012		
Corrected Hedges' g (95% CI)	-0.719 (-1.293, -0.145)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.80		
Percent Change in Fatigue Right Now at Week 24 from Baseline			
n	23	20	
Mean (SD)	48.9 (154.75)	10.8 (53.47)	
Median	0.0	0.0	
Q1, Q3	-50.0, 100.0	-22.6, 28.6	
Min, Max	-100.0, 600.0	-80.0, 150.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7319: Analysis of MPN-SAF Mean Questionnaire Item #19 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	42	22	
n [2]	23	20	
MMRM: Least Squares Mean [SE] (95% CI)	43.55 [21.67] (0.18, 86.92)	35.12 [25.28] (-15.49, 85.72)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	8.43 [33.26] (-58.14, 75.00)		
MMRM: P-value	0.80		
Corrected Hedges' g (95% CI)	0.076 (-0.523, 0.676)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.99		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7320: Analysis of MPN-SAF Mean Questionnaire Item #20 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
BFI0102 - Usual Fatigue Level Past 24 Hours at Baseline		
n	50	29
Mean (SD)	4.1 (2.79)	5.1 (3.05)
Median	4.0	6.0
Q1, Q3	2.0, 6.0	3.0, 8.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
BFI0102 - Usual Fatigue Level Past 24 Hours at Week 4		
n	60	31
Mean (SD)	3.8 (2.33)	5.2 (2.75)
Median	3.0	5.0
Q1, Q3	2.0, 5.0	3.0, 8.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in Usual Fatigue Level Past 24 Hours at Week 4 from Baseline		
n	45	26
Mean (SD)	-0.1 (2.23)	0.2 (2.38)
Median	0.0	0.0
Q1, Q3	-1.0, 1.0	-1.0, 1.0
Min, Max	-6.0, 5.0	-4.0, 7.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7320: Analysis of MPN-SAF Mean Questionnaire Item #20 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	47	27	
n [2]	45	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.26 [0.31] (-0.88, 0.36)	0.45 [0.37] (-0.29, 1.20)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.72 [0.49] (-1.69, 0.25)		
MMRM: P-value	0.15		
Corrected Hedges' g (95% CI)	-0.349 (-0.835, 0.137)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.93		
Percent Change in Usual Fatigue Level Past 24 Hours at Week 4 from Baseline			
n	42	22	
Mean (SD)	13.9 (85.97)	28.3 (153.21)	
Median	0.0	0.0	
Q1, Q3	-33.3, 25.0	-22.2, 14.3	
Min, Max	-100.0, 400.0	-50.0, 700.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	43	23	
n [2]	42	22	
MMRM: Least Squares Mean [SE] (95% CI)	-2.23 [18.42] (-39.09, 34.62)	46.25 [21.98] (2.28, 90.21)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-48.48 [28.89] (-106.27, 9.31)		
MMRM: P-value	0.099		
Corrected Hedges' g (95% CI)	-0.420 (-0.941, 0.101)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.99		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7320: Analysis of MPN-SAF Mean Questionnaire Item #20 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
BFI0102 - Usual Fatigue Level Past 24 Hours at Week 8			
n	57	27	
Mean (SD)	3.9 (2.56)	5.1 (2.38)	
Median	4.0	5.0	
Q1, Q3	2.0, 6.0	4.0, 7.0	
Min, Max	0.0, 9.0	0.0, 10.0	
Return Rate (%)	86%	69%	
Number of Subjects in Risk	61	36	
Return Rate in Risk (%)	93%	75%	
Change in Usual Fatigue Level Past 24 Hours at Week 8 from Baseline			
n	44	24	
Mean (SD)	0.2 (2.45)	0.0 (2.48)	
Median	0.0	-0.5	
Q1, Q3	-1.0, 1.0	-1.0, 1.0	
Min, Max	-5.0, 7.0	-4.0, 8.0	
Difference in Change from Baseline at Week 8			
n [1]	47	27	
n [2]	44	24	
MMRM: Least Squares Mean [SE] (95% CI)	0.14 [0.32] (-0.50, 0.79)	0.39 [0.39] (-0.39, 1.18)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.25 [0.51] (-1.27, 0.76)		
MMRM: P-value	0.62		
Corrected Hedges' g (95% CI)	-0.121 (-0.619, 0.377)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.40		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7320: Analysis of MPN-SAF Mean Questionnaire Item #20 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Usual Fatigue Level Past 24 Hours at Week 8 from Baseline		
n	41	20
Mean (SD)	33.6 (105.49)	28.7 (182.65)
Median	0.0	-13.4
Q1, Q3	-25.0, 33.3	-25.0, 0.0
Min, Max	-100.0, 350.0	-50.0, 800.0
Difference in Percent Change from Baseline at Week 8		
n [1]	43	23
n [2]	41	20
MMRM: Least Squares Mean [SE] (95% CI)	18.25 [19.98] (-21.72, 58.21)	52.33 [24.67] (2.98, 101.68)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-34.08 [31.93] (-97.96, 29.80)	
MMRM: P-value	0.29	
Corrected Hedges' g (95% CI)	-0.275 (-0.811, 0.262)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.34	
BFI0102 - Usual Fatigue Level Past 24 Hours at Week 12		
n	51	30
Mean (SD)	3.9 (2.67)	5.4 (2.62)
Median	4.0	5.0
Q1, Q3	2.0, 6.0	4.0, 8.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	77%	77%
Number of Subjects in Risk	59	33
Return Rate in Risk (%)	86%	91%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7320: Analysis of MPN-SAF Mean Questionnaire Item #20 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Usual Fatigue Level Past 24 Hours at Week 12 from Baseline			
n	37	26	
Mean (SD)	0.4 (2.43)	0.3 (2.71)	
Median	0.0	0.0	
Q1, Q3	-1.0, 1.0	-1.0, 1.0	
Min, Max	-6.0, 6.0	-5.0, 8.0	
Difference in Change from Baseline at Week 12			
n [1]	47	27	
n [2]	37	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.22 [0.38] (-0.55, 0.98)	0.75 [0.44] (-0.13, 1.63)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.53 [0.58] (-1.69, 0.62)		
MMRM: P-value	0.36		
Corrected Hedges' g (95% CI)	-0.230 (-0.734, 0.273)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.99		
Percent Change in Usual Fatigue Level Past 24 Hours at Week 12 from Baseline			
n	34	22	
Mean (SD)	56.7 (159.12)	40.2 (175.11)	
Median	0.0	0.0	
Q1, Q3	-20.0, 33.3	-25.0, 33.3	
Min, Max	-100.0, 600.0	-62.5, 800.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7320: Analysis of MPN-SAF Mean Questionnaire Item #20 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 12			
n [1]	43	23	
n [2]	34	22	
MMRM: Least Squares Mean [SE] (95% CI)	40.06 [23.57] (-7.08, 87.21)	62.26 [28.77] (4.71, 119.81)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-22.20 [37.34] (-96.90, 52.50)		
MMRM: P-value	0.55		
Corrected Hedges' g (95% CI)	-0.160 (-0.698, 0.377)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.90		
BFI0102 - Usual Fatigue Level Past 24 Hours at Week 16			
n	48	30	
Mean (SD)	3.2 (2.47)	5.4 (2.42)	
Median	3.0	5.0	
Q1, Q3	1.0, 5.0	4.0, 8.0	
Min, Max	0.0, 9.0	0.0, 10.0	
Return Rate (%)	73%	77%	
Number of Subjects in Risk	56	33	
Return Rate in Risk (%)	86%	91%	
Change in Usual Fatigue Level Past 24 Hours at Week 16 from Baseline			
n	36	26	
Mean (SD)	-0.7 (2.63)	0.7 (2.64)	
Median	0.0	0.0	
Q1, Q3	-2.0, 1.0	-1.0, 2.0	
Min, Max	-9.0, 3.0	-4.0, 7.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7320: Analysis of MPN-SAF Mean Questionnaire Item #20 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Change from Baseline at Week 16		
n [1]	47	27
n [2]	36	26
MMRM: Least Squares Mean [SE] (95% CI)	-0.47 [0.36] (-1.19, 0.24)	1.06 [0.41] (0.24, 1.87)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.53 [0.54] (-2.61, -0.45)	
MMRM: P-value	0.006	
Corrected Hedges' g (95% CI)	-0.712 (-1.232, -0.193)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.12	
Percent Change in Usual Fatigue Level Past 24 Hours at Week 16 from Baseline		
n	33	22
Mean (SD)	3.0 (83.51)	29.2 (151.53)
Median	0.0	0.0
Q1, Q3	-50.0, 33.3	-11.1, 0.0
Min, Max	-100.0, 300.0	-50.0, 700.0
Difference in Percent Change from Baseline at Week 16		
n [1]	43	23
n [2]	33	22
MMRM: Least Squares Mean [SE] (95% CI)	4.39 [18.62] (-32.85, 41.64)	51.29 [21.87] (7.56, 95.03)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-46.90 [28.90] (-104.71, 10.91)	
MMRM: P-value	0.11	
Corrected Hedges' g (95% CI)	-0.439 (-0.985, 0.106)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.45	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7320: Analysis of MPN-SAF Mean Questionnaire Item #20 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
BFI0102 - Usual Fatigue Level Past 24 Hours at Week 20		
n	44	29
Mean (SD)	3.2 (2.11)	5.2 (2.81)
Median	3.0	5.0
Q1, Q3	2.0, 4.5	3.0, 8.0
Min, Max	0.0, 8.0	0.0, 10.0
Return Rate (%)	67%	74%
Number of Subjects in Risk	51	32
Return Rate in Risk (%)	86%	91%
Change in Usual Fatigue Level Past 24 Hours at Week 20 from Baseline		
n	32	24
Mean (SD)	-0.6 (2.23)	0.1 (2.38)
Median	0.0	0.0
Q1, Q3	-2.0, 1.0	-1.0, 0.5
Min, Max	-7.0, 3.0	-4.0, 7.0
Difference in Change from Baseline at Week 20		
n [1]	47	27
n [2]	32	24
MMRM: Least Squares Mean [SE] (95% CI)	-0.27 [0.33] (-0.94, 0.40)	0.56 [0.38] (-0.20, 1.33)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.83 [0.51] (-1.84, 0.18)	
MMRM: P-value	0.11	
Corrected Hedges' g (95% CI)	-0.435 (-0.970, 0.101)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.43	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7320: Analysis of MPN-SAF Mean Questionnaire Item #20 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Usual Fatigue Level Past 24 Hours at Week 20 from Baseline		
n	29	21
Mean (SD)	-2.3 (77.43)	38.4 (160.32)
Median	0.0	0.0
Q1, Q3	-50.0, 16.7	-20.0, 0.0
Min, Max	-100.0, 300.0	-50.0, 700.0
Difference in Percent Change from Baseline at Week 20		
n [1]	43	23
n [2]	29	21
MMRM: Least Squares Mean [SE] (95% CI)	-1.78 [18.67] (-39.12, 35.57)	58.85 [21.64] (15.57, 102.13)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-60.63 [28.75] (-118.13, -3.13)	
MMRM: P-value	0.039	
Corrected Hedges' g (95% CI)	-0.597 (-1.171, -0.023)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.30	
BFI0102 - Usual Fatigue Level Past 24 Hours at Week 24		
n	41	29
Mean (SD)	3.1 (2.25)	5.9 (2.77)
Median	3.0	6.0
Q1, Q3	2.0, 4.0	4.0, 8.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	62%	74%
Number of Subjects in Risk	48	31
Return Rate in Risk (%)	85%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn20-rt.pdf 24AUG2023:17:01

Table 2.7320: Analysis of MPN-SAF Mean Questionnaire Item #20 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Usual Fatigue Level Past 24 Hours at Week 24 from Baseline			
n	27	23	
Mean (SD)	-0.5 (2.64)	0.7 (2.40)	
Median	0.0	1.0	
Q1, Q3	-2.0, 2.0	-1.0, 2.0	
Min, Max	-7.0, 3.0	-4.0, 8.0	
Difference in Change from Baseline at Week 24			
n [1]	47	27	
n [2]	27	23	
MMRM: Least Squares Mean [SE] (95% CI)		-0.39 [0.34] (-1.07, 0.30)	1.29 [0.38] (0.54, 2.05)
MMRM: Least Squares Mean Difference [SE] (95% CI)		-1.68 [0.51] (-2.69, -0.66)	
MMRM: P-value		0.002	
Corrected Hedges' g (95% CI)		-0.920 (-1.504, -0.335)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value		0.17	
Percent Change in Usual Fatigue Level Past 24 Hours at Week 24 from Baseline			
n	24	20	
Mean (SD)	12.0 (94.54)	53.2 (183.01)	
Median	0.0	6.3	
Q1, Q3	-50.0, 50.0	-11.1, 18.3	
Min, Max	-100.0, 300.0	-50.0, 800.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7320: Analysis of MPN-SAF Mean Questionnaire Item #20 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	43	23	
n [2]	24	20	
MMRM: Least Squares Mean [SE] (95% CI)	6.00 [20.77] (-35.55, 47.55)	73.64 [23.64] (26.36, 120.92)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-67.64 [31.62] (-130.88, -4.40)		
MMRM: P-value	0.036		
Corrected Hedges' g (95% CI)	-0.641 (-1.250, -0.033)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.28		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

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Table 2.7321: Analysis of MPN-SAF Mean Questionnaire Item #21 Score and Change from Baseline

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
BFI0103 - Worst Fatigue Level Past 24 Hours at Baseline		
n	50	29
Mean (SD)	4.7 (3.17)	5.7 (3.02)
Median	4.0	6.0
Q1, Q3	2.0, 8.0	4.0, 8.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
BFI0103 - Worst Fatigue Level Past 24 Hours at Week 4		
n	60	31
Mean (SD)	4.5 (2.63)	6.1 (2.98)
Median	4.0	7.0
Q1, Q3	3.0, 7.0	4.0, 8.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in Worst Fatigue Level Past 24 Hours at Week 4 from Baseline		
n	45	26
Mean (SD)	0.0 (2.71)	0.2 (2.81)
Median	0.0	0.0
Q1, Q3	-1.0, 2.0	-2.0, 1.0
Min, Max	-6.0, 6.0	-4.0, 10.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7321: Analysis of MPN-SAF Mean Questionnaire Item #21 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	47	27	
n [2]	45	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.28 [0.36] (-0.99, 0.43)	0.43 [0.44] (-0.45, 1.31)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.71 [0.57] (-1.84, 0.42)		
MMRM: P-value	0.22		
Corrected Hedges' g (95% CI)	-0.300 (-0.785, 0.186)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.83		
Percent Change in Worst Fatigue Level Past 24 Hours at Week 4 from Baseline			
n	41	22	
Mean (SD)	26.4 (120.19)	-4.3 (37.10)	
Median	0.0	-5.6	
Q1, Q3	-25.0, 33.3	-22.2, 0.0	
Min, Max	-100.0, 600.0	-66.7, 100.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	42	23	
n [2]	41	22	
MMRM: Least Squares Mean [SE] (95% CI)	21.95 [15.02] (-8.11, 52.01)	4.10 [19.46] (-34.84, 43.04)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	17.85 [24.75] (-31.67, 67.37)		
MMRM: P-value	0.47		
Corrected Hedges' g (95% CI)	0.186 (-0.333, 0.706)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.72		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7321: Analysis of MPN-SAF Mean Questionnaire Item #21 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
BFI0103 - Worst Fatigue Level Past 24 Hours at Week 8		
n	57	27
Mean (SD)	4.3 (2.84)	5.7 (2.46)
Median	4.0	6.0
Q1, Q3	2.0, 7.0	4.0, 8.0
Min, Max	0.0, 10.0	2.0, 10.0
Return Rate (%)	86%	69%
Number of Subjects in Risk	61	36
Return Rate in Risk (%)	93%	75%
Change in Worst Fatigue Level Past 24 Hours at Week 8 from Baseline		
n	44	24
Mean (SD)	0.0 (2.25)	-0.1 (3.01)
Median	0.0	-1.0
Q1, Q3	-1.5, 1.0	-2.0, 1.5
Min, Max	-5.0, 7.0	-4.0, 10.0
Difference in Change from Baseline at Week 8		
n [1]	47	27
n [2]	44	24
MMRM: Least Squares Mean [SE] (95% CI)	-0.27 [0.33] (-0.93, 0.39)	0.32 [0.41] (-0.50, 1.14)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.59 [0.53] (-1.64, 0.46)	
MMRM: P-value	0.27	
Corrected Hedges' g (95% CI)	-0.273 (-0.772, 0.227)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.95	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn21-rt.pdf 24AUG2023:17:01

Table 2.7321: Analysis of MPN-SAF Mean Questionnaire Item #21 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in Worst Fatigue Level Past 24 Hours at Week 8 from Baseline			
n	40	20	
Mean (SD)	24.3 (94.01)	-12.7 (27.55)	
Median	0.0	-12.5	
Q1, Q3	-22.2, 29.2	-33.3, 0.0	
Min, Max	-100.0, 350.0	-60.0, 33.3	
Difference in Percent Change from Baseline at Week 8			
n [1]	42	23	
n [2]	40	20	
MMRM: Least Squares Mean [SE] (95% CI)	17.53 [12.22] (-6.92, 41.98)	-1.31 [15.81] (-32.95, 30.33)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	18.84 [20.14] (-21.45, 59.14)		
MMRM: P-value	0.35		
Corrected Hedges' g (95% CI)	0.247 (-0.291, 0.786)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.42		
BFI0103 - Worst Fatigue Level Past 24 Hours at Week 12			
n	51	30	
Mean (SD)	4.7 (2.87)	5.7 (2.60)	
Median	5.0	5.0	
Q1, Q3	2.0, 7.0	4.0, 8.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	77%	77%	
Number of Subjects in Risk	59	33	
Return Rate in Risk (%)	86%	91%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn21-rt.pdf 24AUG2023:17:01

Table 2.7321: Analysis of MPN-SAF Mean Questionnaire Item #21 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Worst Fatigue Level Past 24 Hours at Week 12 from Baseline		
n	37	26
Mean (SD)	0.6 (2.73)	0.0 (2.35)
Median	0.0	0.0
Q1, Q3	-1.0, 2.0	-1.0, 2.0
Min, Max	-5.0, 7.0	-5.0, 4.0
Difference in Change from Baseline at Week 12		
n [1]	47	27
n [2]	37	26
MMRM: Least Squares Mean [SE] (95% CI)	0.06 [0.38] (-0.70, 0.81)	0.36 [0.43] (-0.50, 1.23)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.31 [0.58] (-1.46, 0.84)	
MMRM: P-value	0.59	
Corrected Hedges' g (95% CI)	-0.134 (-0.636, 0.368)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.97	
Percent Change in Worst Fatigue Level Past 24 Hours at Week 12 from Baseline		
n	33	22
Mean (SD)	46.6 (149.41)	-3.4 (35.59)
Median	0.0	0.0
Q1, Q3	-25.0, 50.0	-22.2, 12.5
Min, Max	-100.0, 600.0	-66.7, 80.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7321: Analysis of MPN-SAF Mean Questionnaire Item #21 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 12			
n [1]	42	23	
n [2]	33	22	
MMRM: Least Squares Mean [SE] (95% CI)	36.50 [17.90] (0.70, 72.31)	9.18 [22.79] (-36.42, 54.79)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	27.32 [29.08] (-30.86, 85.51)		
MMRM: P-value	0.35		
Corrected Hedges' g (95% CI)	0.258 (-0.284, 0.799)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.97		
BFI0103 - Worst Fatigue Level Past 24 Hours at Week 16			
n	48	30	
Mean (SD)	3.6 (2.70)	6.0 (2.79)	
Median	3.0	6.0	
Q1, Q3	1.5, 6.5	4.0, 8.0	
Min, Max	0.0, 9.0	0.0, 10.0	
Return Rate (%)	73%	77%	
Number of Subjects in Risk	56	33	
Return Rate in Risk (%)	86%	91%	
Change in Worst Fatigue Level Past 24 Hours at Week 16 from Baseline			
n	36	26	
Mean (SD)	-0.8 (2.58)	0.7 (2.84)	
Median	-0.5	0.0	
Q1, Q3	-2.0, 1.0	-1.0, 2.0	
Min, Max	-9.0, 4.0	-4.0, 10.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn21-rt.pdf 24AUG2023:17:01

Table 2.7321: Analysis of MPN-SAF Mean Questionnaire Item #21 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	47	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.84 [0.37] (-1.57, -0.11)	1.11 [0.43] (0.25, 1.97)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.95 [0.56] (-3.07, -0.82)		
MMRM: P-value	< 0.001		
Corrected Hedges' g (95% CI)	-0.874 (-1.401, -0.346)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.043		
Percent Change in Worst Fatigue Level Past 24 Hours at Week 16 from Baseline			
n	32	22	
Mean (SD)	-2.3 (80.36)	-0.4 (31.76)	
Median	-21.1	0.0	
Q1, Q3	-50.0, 26.7	-20.0, 14.3	
Min, Max	-100.0, 300.0	-66.7, 66.7	
Difference in Percent Change from Baseline at Week 16			
n [1]	42	23	
n [2]	32	22	
MMRM: Least Squares Mean [SE] (95% CI)	-1.74 [11.50] (-24.76, 21.27)	10.52 [13.77] (-17.02, 38.07)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-12.26 [18.12] (-48.52, 24.00)		
MMRM: P-value	0.50		
Corrected Hedges' g (95% CI)	-0.186 (-0.730, 0.358)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.12		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7321: Analysis of MPN-SAF Mean Questionnaire Item #21 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
BFI0103 - Worst Fatigue Level Past 24 Hours at Week 20			
n	44	29	
Mean (SD)	3.8 (2.35)	5.6 (3.07)	
Median	4.0	5.0	
Q1, Q3	2.0, 5.0	4.0, 8.0	
Min, Max	0.0, 8.0	0.0, 10.0	
Return Rate (%)	67%	74%	
Number of Subjects in Risk	51	32	
Return Rate in Risk (%)	86%	91%	
Change in Worst Fatigue Level Past 24 Hours at Week 20 from Baseline			
n	32	24	
Mean (SD)	-0.6 (2.47)	-0.1 (2.42)	
Median	0.0	0.0	
Q1, Q3	-2.5, 1.0	-1.5, 1.0	
Min, Max	-6.0, 3.0	-5.0, 5.0	
Difference in Change from Baseline at Week 20			
n [1]	47	27	
n [2]	32	24	
MMRM: Least Squares Mean [SE] (95% CI)	-0.60 [0.37] (-1.33, 0.13)	0.36 [0.41] (-0.47, 1.19)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.96 [0.55] (-2.06, 0.14)		
MMRM: P-value	0.087		
Corrected Hedges' g (95% CI)	-0.460 (-0.996, 0.076)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.44		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

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Table 2.7321: Analysis of MPN-SAF Mean Questionnaire Item #21 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in Worst Fatigue Level Past 24 Hours at Week 20 from Baseline			
n	28	21	
Mean (SD)	3.8 (78.99)	-2.8 (39.22)	
Median	-10.0	-11.1	
Q1, Q3	-44.4, 33.3	-22.2, 12.5	
Min, Max	-100.0, 300.0	-100.0, 66.7	
Difference in Percent Change from Baseline at Week 20			
n [1]	42	23	
n [2]	28	21	
MMRM: Least Squares Mean [SE] (95% CI)	3.30 [10.97] (-18.64, 25.25)	8.17 [12.69] (-17.22, 33.56)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-4.86 [16.94] (-38.77, 29.04)		
MMRM: P-value	0.78		
Corrected Hedges' g (95% CI)	-0.082 (-0.648, 0.484)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.42		
BFI0103 - Worst Fatigue Level Past 24 Hours at Week 24			
n	41	29	
Mean (SD)	3.6 (2.68)	6.1 (2.94)	
Median	3.0	7.0	
Q1, Q3	2.0, 5.0	4.0, 8.0	
Min, Max	0.0, 9.0	0.0, 10.0	
Return Rate (%)	62%	74%	
Number of Subjects in Risk	48	31	
Return Rate in Risk (%)	85%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7321: Analysis of MPN-SAF Mean Questionnaire Item #21 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Worst Fatigue Level Past 24 Hours at Week 24 from Baseline		
n	27	23
Mean (SD)	-0.6 (2.68)	0.3 (1.69)
Median	0.0	0.0
Q1, Q3	-2.0, 1.0	0.0, 1.0
Min, Max	-7.0, 4.0	-3.0, 4.0
Difference in Change from Baseline at Week 24		
n [1]	47	27
n [2]	27	23
MMRM: Least Squares Mean [SE] (95% CI)	-0.97 [0.36] (-1.70, -0.25)	0.95 [0.40] (0.15, 1.74)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.92 [0.54] (-3.00, -0.84)	
MMRM: P-value	< 0.001	
Corrected Hedges' g (95% CI)	-0.993 (-1.583, -0.404)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.12	
Percent Change in Worst Fatigue Level Past 24 Hours at Week 24 from Baseline		
n	23	20
Mean (SD)	3.3 (73.76)	4.6 (26.49)
Median	0.0	0.0
Q1, Q3	-44.4, 33.3	-5.6, 17.1
Min, Max	-100.0, 200.0	-60.0, 66.7

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7321: Analysis of MPN-SAF Mean Questionnaire Item #21 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	42	23	
n [2]	23	20	
MMRM: Least Squares Mean [SE] (95% CI)	-2.99 [9.93] (-22.86, 16.88)		18.11 [11.08] (-4.06, 40.28)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-21.10 [15.10] (-51.31, 9.12)		
MMRM: P-value	0.17		
Corrected Hedges' g (95% CI)	-0.427 (-1.033, 0.179)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.20		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7322: Analysis of MPN-SAF Mean Questionnaire Item #22 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
BFI0104 - Interfered Activity Past 24 Hours at Baseline		
n	50	29
Mean (SD)	3.7 (3.05)	4.5 (3.09)
Median	3.0	5.0
Q1, Q3	1.0, 7.0	3.0, 7.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
BFI0104 - Interfered Activity Past 24 Hours at Week 4		
n	60	31
Mean (SD)	4.1 (2.84)	5.1 (2.82)
Median	4.0	5.0
Q1, Q3	2.0, 7.0	3.0, 7.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in Interfered Activity Past 24 Hours at Week 4 from Baseline		
n	45	26
Mean (SD)	0.9 (2.92)	0.5 (2.61)
Median	1.0	0.0
Q1, Q3	0.0, 2.0	-1.0, 1.0
Min, Max	-7.0, 8.0	-4.0, 7.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7322: Analysis of MPN-SAF Mean Questionnaire Item #22 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	47	27	
n [2]	45	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.88 [0.36] (0.17, 1.59)	0.80 [0.43] (-0.06, 1.66)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.08 [0.56] (-1.04, 1.20)		
MMRM: P-value	0.89		
Corrected Hedges' g (95% CI)	0.034 (-0.449, 0.516)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.27		
Percent Change in Interfered Activity Past 24 Hours at Week 4 from Baseline			
n	38	21	
Mean (SD)	60.0 (168.88)	36.7 (163.15)	
Median	0.0	0.0	
Q1, Q3	-20.0, 66.7	-22.2, 20.0	
Min, Max	-100.0, 600.0	-100.0, 700.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	39	22	
n [2]	38	21	
MMRM: Least Squares Mean [SE] (95% CI)	48.57 [26.97] (-5.49, 102.63)	53.90 [31.25] (-8.72, 116.53)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-5.34 [41.24] (-87.98, 77.30)		
MMRM: P-value	0.90		
Corrected Hedges' g (95% CI)	-0.033 (-0.566, 0.500)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.44		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7322: Analysis of MPN-SAF Mean Questionnaire Item #22 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
BFI0104 - Interfered Activity Past 24 Hours at Week 8		
n	57	27
Mean (SD)	4.1 (2.96)	5.0 (2.67)
Median	4.0	5.0
Q1, Q3	2.0, 7.0	3.0, 7.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	86%	69%
Number of Subjects in Risk	61	36
Return Rate in Risk (%)	93%	75%
Change in Interfered Activity Past 24 Hours at Week 8 from Baseline		
n	44	24
Mean (SD)	0.9 (2.88)	0.4 (2.30)
Median	1.0	0.5
Q1, Q3	-1.0, 2.0	-0.5, 2.0
Min, Max	-8.0, 9.0	-7.0, 5.0
Difference in Change from Baseline at Week 8		
n [1]	47	27
n [2]	44	24
MMRM: Least Squares Mean [SE] (95% CI)	0.96 [0.35] (0.26, 1.67)	0.98 [0.43] (0.13, 1.84)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.02 [0.55] (-1.12, 1.08)	
MMRM: P-value	0.98	
Corrected Hedges' g (95% CI)	-0.008 (-0.505, 0.490)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.80	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7322: Analysis of MPN-SAF Mean Questionnaire Item #22 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in Interfered Activity Past 24 Hours at Week 8 from Baseline			
n	37	19	
Mean (SD)	65.1 (161.54)	8.1 (37.61)	
Median	0.0	0.0	
Q1, Q3	-22.2, 100.0	-14.3, 33.3	
Min, Max	-100.0, 600.0	-77.8, 66.7	
Difference in Percent Change from Baseline at Week 8			
n [1]	39	22	
n [2]	37	19	
MMRM: Least Squares Mean [SE] (95% CI)		52.70 [23.65] (5.31, 100.09)	58.83 [26.34] (6.04, 111.61)
MMRM: Least Squares Mean Difference [SE] (95% CI)		-6.12 [35.20] (-76.67, 64.42)	
MMRM: P-value	0.86		
Corrected Hedges' g (95% CI)	-0.045 (-0.598, 0.508)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	1.00		
BFI0104 - Interfered Activity Past 24 Hours at Week 12			
n	51	30	
Mean (SD)	3.8 (2.87)	5.2 (2.82)	
Median	3.0	5.0	
Q1, Q3	1.0, 6.0	3.0, 7.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	77%	77%	
Number of Subjects in Risk	59	33	
Return Rate in Risk (%)	86%	91%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7322: Analysis of MPN-SAF Mean Questionnaire Item #22 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Interfered Activity Past 24 Hours at Week 12 from Baseline		
n	37	26
Mean (SD)	0.8 (3.00)	0.8 (2.10)
Median	1.0	0.0
Q1, Q3	-1.0, 3.0	0.0, 2.0
Min, Max	-6.0, 6.0	-3.0, 5.0
Difference in Change from Baseline at Week 12		
n [1]	47	27
n [2]	37	26
MMRM: Least Squares Mean [SE] (95% CI)	0.79 [0.37] (0.05, 1.53)	1.17 [0.43] (0.32, 2.03)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.38 [0.56] (-1.51, 0.74)	
MMRM: P-value	0.50	
Corrected Hedges' g (95% CI)	-0.170 (-0.673, 0.332)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.86	
Percent Change in Interfered Activity Past 24 Hours at Week 12 from Baseline		
n	31	21
Mean (SD)	91.3 (190.57)	32.2 (115.11)
Median	11.1	0.0
Q1, Q3	-33.3, 150.0	-11.1, 40.0
Min, Max	-100.0, 600.0	-66.7, 500.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn22-rt.pdf 24AUG2023:17:01

Table 2.7322: Analysis of MPN-SAF Mean Questionnaire Item #22 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 12			
n [1]	39	22	
n [2]	31	21	
MMRM: Least Squares Mean [SE] (95% CI)	71.42 [25.66] (20.00, 122.84)		56.48 [28.47] (-0.58, 113.53)
MMRM: Least Squares Mean Difference [SE] (95% CI)	14.95 [38.24] (-61.68, 91.57)		
MMRM: P-value	0.70		
Corrected Hedges' g (95% CI)	0.107 (-0.448, 0.661)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.75		
BFI0104 - Interfered Activity Past 24 Hours at Week 16			
n	48	30	
Mean (SD)	3.1 (2.68)	5.0 (3.02)	
Median	2.0	4.5	
Q1, Q3	1.0, 5.0	3.0, 8.0	
Min, Max	0.0, 9.0	0.0, 10.0	
Return Rate (%)	73%	77%	
Number of Subjects in Risk	56	33	
Return Rate in Risk (%)	86%	91%	
Change in Interfered Activity Past 24 Hours at Week 16 from Baseline			
n	36	26	
Mean (SD)	-0.3 (2.88)	1.0 (2.30)	
Median	0.0	0.0	
Q1, Q3	-2.0, 1.0	-1.0, 3.0	
Min, Max	-6.0, 6.0	-3.0, 6.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7322: Analysis of MPN-SAF Mean Questionnaire Item #22 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	47	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.12 [0.39] (-0.65, 0.90)	1.37 [0.44] (0.48, 2.26)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.25 [0.59] (-2.42, -0.08)		
MMRM: P-value	0.037		
Corrected Hedges' g (95% CI)	-0.535 (-1.048, -0.022)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.10		
Percent Change in Interfered Activity Past 24 Hours at Week 16 from Baseline			
n	30	21	
Mean (SD)	35.4 (178.11)	27.8 (116.94)	
Median	0.0	0.0	
Q1, Q3	-66.7, 16.7	-11.1, 16.7	
Min, Max	-100.0, 600.0	-100.0, 500.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	39	22	
n [2]	30	21	
MMRM: Least Squares Mean [SE] (95% CI)	38.42 [26.53] (-14.74, 91.59)	52.05 [30.13] (-8.34, 112.43)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-13.62 [40.06] (-93.91, 66.66)		
MMRM: P-value	0.74		
Corrected Hedges' g (95% CI)	-0.094 (-0.652, 0.464)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.34		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7322: Analysis of MPN-SAF Mean Questionnaire Item #22 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
BFI0104 - Interfered Activity Past 24 Hours at Week 20			
n	44	29	
Mean (SD)	3.0 (2.29)	5.0 (2.73)	
Median	3.0	5.0	
Q1, Q3	1.5, 4.0	3.0, 7.0	
Min, Max	0.0, 9.0	0.0, 10.0	
Return Rate (%)	67%	74%	
Number of Subjects in Risk	51	32	
Return Rate in Risk (%)	86%	91%	
Change in Interfered Activity Past 24 Hours at Week 20 from Baseline			
n	32	24	
Mean (SD)	0.0 (2.75)	0.4 (2.38)	
Median	0.0	0.0	
Q1, Q3	-2.0, 2.0	-1.0, 1.5	
Min, Max	-6.0, 6.0	-4.0, 6.0	
Difference in Change from Baseline at Week 20			
n [1]	47	27	
n [2]	32	24	
MMRM: Least Squares Mean [SE] (95% CI)		0.32 [0.36] (-0.40, 1.04)	0.79 [0.40] (-0.02, 1.59)
MMRM: Least Squares Mean Difference [SE] (95% CI)		-0.47 [0.54] (-1.54, 0.61)	
MMRM: P-value		0.39	
Corrected Hedges' g (95% CI)		-0.229 (-0.760, 0.302)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value		0.64	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7322: Analysis of MPN-SAF Mean Questionnaire Item #22 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in Interfered Activity Past 24 Hours at Week 20 from Baseline			
n	26	20	
Mean (SD)	35.3 (161.11)	39.3 (143.21)	
Median	0.0	0.0	
Q1, Q3	-50.0, 33.3	-20.0, 8.3	
Min, Max	-100.0, 600.0	-44.4, 600.0	
Difference in Percent Change from Baseline at Week 20			
n [1]	39	22	
n [2]	26	20	
MMRM: Least Squares Mean [SE] (95% CI)		25.43 [28.41] (-31.49, 82.36)	62.53 [29.66] (3.09, 121.96)
MMRM: Least Squares Mean Difference [SE] (95% CI)		-37.09 [40.79] (-118.85, 44.66)	
MMRM: P-value		0.37	
Corrected Hedges' g (95% CI)		-0.261 (-0.846, 0.324)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value		0.29	
BFI0104 - Interfered Activity Past 24 Hours at Week 24			
n	41	29	
Mean (SD)	3.2 (2.72)	5.2 (3.02)	
Median	3.0	5.0	
Q1, Q3	1.0, 5.0	3.0, 8.0	
Min, Max	0.0, 9.0	0.0, 10.0	
Return Rate (%)	62%	74%	
Number of Subjects in Risk	48	31	
Return Rate in Risk (%)	85%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7322: Analysis of MPN-SAF Mean Questionnaire Item #22 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Interfered Activity Past 24 Hours at Week 24 from Baseline		
n	27	23
Mean (SD)	0.1 (3.47)	1.0 (1.73)
Median	0.0	1.0
Q1, Q3	-2.0, 3.0	0.0, 2.0
Min, Max	-6.0, 6.0	-3.0, 5.0
Difference in Change from Baseline at Week 24		
n [1]	47	27
n [2]	27	23
MMRM: Least Squares Mean [SE] (95% CI)	0.34 [0.41] (-0.47, 1.16)	1.52 [0.45] (0.62, 2.43)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.18 [0.61] (-2.39, 0.03)	
MMRM: P-value	0.056	
Corrected Hedges' g (95% CI)	-0.543 (-1.109, 0.023)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.24	
Percent Change in Interfered Activity Past 24 Hours at Week 24 from Baseline		
n	21	19
Mean (SD)	66.7 (234.17)	45.0 (99.15)
Median	-25.0	14.3
Q1, Q3	-66.7, 50.0	0.0, 50.0
Min, Max	-100.0, 600.0	-33.3, 400.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7322: Analysis of MPN-SAF Mean Questionnaire Item #22 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	39	22	
n [2]	21	19	
MMRM: Least Squares Mean [SE] (95% CI)	36.66 [27.96] (-19.38, 92.70)	68.27 [31.56] (5.03, 131.52)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-31.61 [42.09] (-115.95, 52.73)		
MMRM: P-value	0.46		
Corrected Hedges' g (95% CI)	-0.233 (-0.856, 0.389)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.095		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

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Table 2.7323: Analysis of MPN-SAF Mean Questionnaire Item #23 Score and Change from Baseline

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
BFI0105 - Interfered Mood Past 24 Hours at Baseline		
n	50	29
Mean (SD)	3.5 (2.97)	3.5 (3.10)
Median	3.0	3.0
Q1, Q3	1.0, 6.0	1.0, 6.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
BFI0105 - Interfered Mood Past 24 Hours at Week 4		
n	60	31
Mean (SD)	3.3 (2.75)	3.7 (3.16)
Median	3.0	4.0
Q1, Q3	1.0, 5.5	0.0, 5.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in Interfered Mood Past 24 Hours at Week 4 from Baseline		
n	45	26
Mean (SD)	0.3 (3.05)	0.0 (2.68)
Median	0.0	0.0
Q1, Q3	-2.0, 2.0	-2.0, 2.0
Min, Max	-7.0, 7.0	-4.0, 6.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7323: Analysis of MPN-SAF Mean Questionnaire Item #23 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	47	27	
n [2]	45	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.58 [0.36] (-0.15, 1.31)	0.02 [0.45] (-0.87, 0.90)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.57 [0.57] (-0.58, 1.71)		
MMRM: P-value	0.33		
Corrected Hedges' g (95% CI)	0.235 (-0.250, 0.719)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.41		
Percent Change in Interfered Mood Past 24 Hours at Week 4 from Baseline			
n	35	19	
Mean (SD)	52.0 (182.46)	-3.8 (102.47)	
Median	0.0	-28.6	
Q1, Q3	-42.9, 60.0	-100.0, 25.0	
Min, Max	-100.0, 600.0	-100.0, 300.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	36	20	
n [2]	35	19	
MMRM: Least Squares Mean [SE] (95% CI)	54.31 [26.39] (1.31, 107.31)	-5.24 [33.31] (-72.15, 61.67)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	59.55 [42.21] (-25.24, 144.34)		
MMRM: P-value	0.16		
Corrected Hedges' g (95% CI)	0.385 (-0.178, 0.948)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.23		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7323: Analysis of MPN-SAF Mean Questionnaire Item #23 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
BFI0105 - Interfered Mood Past 24 Hours at Week 8			
n	57	27	
Mean (SD)	3.3 (2.81)	3.7 (2.73)	
Median	3.0	4.0	
Q1, Q3	1.0, 5.0	1.0, 6.0	
Min, Max	0.0, 9.0	0.0, 10.0	
Return Rate (%)	86%	69%	
Number of Subjects in Risk	61	36	
Return Rate in Risk (%)	93%	75%	
Change in Interfered Mood Past 24 Hours at Week 8 from Baseline			
n	44	24	
Mean (SD)	0.3 (2.72)	0.2 (2.08)	
Median	0.0	0.0	
Q1, Q3	-1.0, 1.5	-0.5, 1.5	
Min, Max	-8.0, 8.0	-5.0, 4.0	
Difference in Change from Baseline at Week 8			
n [1]	47	27	
n [2]	44	24	
MMRM: Least Squares Mean [SE] (95% CI)	0.66 [0.35] (-0.05, 1.36)	0.34 [0.44] (-0.53, 1.22)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.31 [0.56] (-0.80, 1.43)		
MMRM: P-value	0.58		
Corrected Hedges' g (95% CI)	0.136 (-0.362, 0.634)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.75		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

GSK Oncology

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Table 2.7323: Analysis of MPN-SAF Mean Questionnaire Item #23 Score and Change from Baseline

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in Interfered Mood Past 24 Hours at Week 8 from Baseline			
n	34	18	
Mean (SD)	25.6 (110.68)	15.7 (65.81)	
Median	0.0	0.0	
Q1, Q3	-33.3, 40.0	-25.0, 50.0	
Min, Max	-100.0, 400.0	-66.7, 150.0	
Difference in Percent Change from Baseline at Week 8			
n [1]	36	20	
n [2]	34	18	
MMRM: Least Squares Mean [SE] (95% CI)	26.82 [17.82] (-8.96, 62.60)	20.93 [21.06] (-21.37, 63.23)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	5.89 [26.77] (-47.88, 59.67)		
MMRM: P-value	0.83		
Corrected Hedges' g (95% CI)	0.059 (-0.513, 0.630)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.47		
BFI0105 - Interfered Mood Past 24 Hours at Week 12			
n	51	30	
Mean (SD)	2.8 (2.59)	3.5 (2.99)	
Median	3.0	3.0	
Q1, Q3	0.0, 5.0	1.0, 6.0	
Min, Max	0.0, 8.0	0.0, 10.0	
Return Rate (%)	77%	77%	
Number of Subjects in Risk	59	33	
Return Rate in Risk (%)	86%	91%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7323: Analysis of MPN-SAF Mean Questionnaire Item #23 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Interfered Mood Past 24 Hours at Week 12 from Baseline		
n	37	26
Mean (SD)	0.0 (2.62)	0.2 (2.22)
Median	0.0	0.0
Q1, Q3	-2.0, 2.0	-1.0, 2.0
Min, Max	-5.0, 6.0	-4.0, 5.0
Difference in Change from Baseline at Week 12		
n [1]	47	27
n [2]	37	26
MMRM: Least Squares Mean [SE] (95% CI)	0.23 [0.37] (-0.50, 0.96)	0.23 [0.41] (-0.59, 1.05)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.00 [0.55] (-1.10, 1.09)	
MMRM: P-value	0.99	
Corrected Hedges' g (95% CI)	-0.002 (-0.504, 0.500)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.86	
Percent Change in Interfered Mood Past 24 Hours at Week 12 from Baseline		
n	28	19
Mean (SD)	44.9 (159.38)	5.3 (77.87)
Median	-13.4	0.0
Q1, Q3	-50.0, 83.3	-50.0, 50.0
Min, Max	-100.0, 600.0	-100.0, 200.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7323: Analysis of MPN-SAF Mean Questionnaire Item #23 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 12			
n [1]	36	20	
n [2]	28	19	
MMRM: Least Squares Mean [SE] (95% CI)	34.85 [23.53] (-12.42, 82.12)		10.48 [27.43] (-44.62, 65.58)
MMRM: Least Squares Mean Difference [SE] (95% CI)	24.37 [35.71] (-47.35, 96.10)		
MMRM: P-value	0.50		
Corrected Hedges' g (95% CI)	0.196 (-0.388, 0.779)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.59		
BFI0105 - Interfered Mood Past 24 Hours at Week 16			
n	48	30	
Mean (SD)	2.6 (2.58)	3.7 (3.17)	
Median	2.0	3.0	
Q1, Q3	0.0, 4.5	1.0, 6.0	
Min, Max	0.0, 9.0	0.0, 10.0	
Return Rate (%)	73%	77%	
Number of Subjects in Risk	56	33	
Return Rate in Risk (%)	86%	91%	
Change in Interfered Mood Past 24 Hours at Week 16 from Baseline			
n	36	26	
Mean (SD)	-0.5 (2.84)	0.7 (2.96)	
Median	0.0	0.0	
Q1, Q3	-2.0, 1.0	-1.0, 2.0	
Min, Max	-6.0, 6.0	-7.0, 8.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7323: Analysis of MPN-SAF Mean Questionnaire Item #23 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	47	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.07 [0.42] (-0.78, 0.91)	0.80 [0.49] (-0.18, 1.78)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.73 [0.65] (-2.02, 0.56)		
MMRM: P-value	0.26		
Corrected Hedges' g (95% CI)	-0.286 (-0.793, 0.220)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.31		
Percent Change in Interfered Mood Past 24 Hours at Week 16 from Baseline			
n	27	19	
Mean (SD)	2.2 (115.35)	27.3 (117.70)	
Median	-16.7	0.0	
Q1, Q3	-75.0, 40.0	-50.0, 66.7	
Min, Max	-100.0, 400.0	-100.0, 400.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	36	20	
n [2]	27	19	
MMRM: Least Squares Mean [SE] (95% CI)	15.85 [23.81] (-31.97, 63.67)	31.85 [27.43] (-23.25, 86.95)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-16.00 [35.88] (-88.07, 56.08)		
MMRM: P-value	0.66		
Corrected Hedges' g (95% CI)	-0.129 (-0.716, 0.459)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.47		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7323: Analysis of MPN-SAF Mean Questionnaire Item #23 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
BFI0105 - Interfered Mood Past 24 Hours at Week 20			
n	44	29	
Mean (SD)	2.5 (2.23)	3.9 (3.01)	
Median	2.0	3.0	
Q1, Q3	0.0, 4.0	2.0, 6.0	
Min, Max	0.0, 8.0	0.0, 10.0	
Return Rate (%)	67%	74%	
Number of Subjects in Risk	51	32	
Return Rate in Risk (%)	86%	91%	
Change in Interfered Mood Past 24 Hours at Week 20 from Baseline			
n	32	24	
Mean (SD)	-0.4 (2.64)	0.5 (2.43)	
Median	0.0	0.0	
Q1, Q3	-1.5, 1.0	-0.5, 2.0	
Min, Max	-7.0, 4.0	-6.0, 6.0	
Difference in Change from Baseline at Week 20			
n [1]	47	27	
n [2]	32	24	
MMRM: Least Squares Mean [SE] (95% CI)	0.26 [0.40] (-0.53, 1.06)	0.78 [0.45] (-0.11, 1.67)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.52 [0.60] (-1.71, 0.68)		
MMRM: P-value	0.39		
Corrected Hedges' g (95% CI)	-0.228 (-0.759, 0.303)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.16		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn23-rt.pdf 24AUG2023:17:02

Table 2.7323: Analysis of MPN-SAF Mean Questionnaire Item #23 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in Interfered Mood Past 24 Hours at Week 20 from Baseline			
n	23	18	
Mean (SD)	6.0 (121.69)	22.9 (81.66)	
Median	-25.0	0.0	
Q1, Q3	-57.1, 16.7	-12.5, 50.0	
Min, Max	-100.0, 400.0	-85.7, 300.0	
Difference in Percent Change from Baseline at Week 20			
n [1]	36	20	
n [2]	23	18	
MMRM: Least Squares Mean [SE] (95% CI)		20.92 [21.19] (-21.63, 63.48)	30.76 [23.26] (-15.96, 77.48)
MMRM: Least Squares Mean Difference [SE] (95% CI)		-9.84 [30.98] (-72.06, 52.38)	
MMRM: P-value	0.75		
Corrected Hedges' g (95% CI)	-0.096 (-0.713, 0.521)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.12		
BFI0105 - Interfered Mood Past 24 Hours at Week 24			
n	41	29	
Mean (SD)	2.5 (2.36)	3.7 (3.22)	
Median	2.0	3.0	
Q1, Q3	0.0, 4.0	1.0, 6.0	
Min, Max	0.0, 8.0	0.0, 10.0	
Return Rate (%)	62%	74%	
Number of Subjects in Risk	48	31	
Return Rate in Risk (%)	85%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7323: Analysis of MPN-SAF Mean Questionnaire Item #23 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Interfered Mood Past 24 Hours at Week 24 from Baseline		
n	27	23
Mean (SD)	-0.6 (2.96)	-0.1 (1.93)
Median	0.0	0.0
Q1, Q3	-3.0, 2.0	-1.0, 1.0
Min, Max	-7.0, 4.0	-7.0, 3.0
Difference in Change from Baseline at Week 24		
n [1]	47	27
n [2]	27	23
MMRM: Least Squares Mean [SE] (95% CI)	0.02 [0.41] (-0.81, 0.84)	0.28 [0.45] (-0.61, 1.17)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.26 [0.61] (-1.47, 0.95)	
MMRM: P-value	0.67	
Corrected Hedges' g (95% CI)	-0.120 (-0.677, 0.437)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.80	
Percent Change in Interfered Mood Past 24 Hours at Week 24 from Baseline		
n	18	18
Mean (SD)	-1.0 (107.84)	0.8 (55.94)
Median	-38.1	0.0
Q1, Q3	-75.0, 16.7	-25.0, 33.3
Min, Max	-100.0, 300.0	-100.0, 150.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7323: Analysis of MPN-SAF Mean Questionnaire Item #23 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	**36**	**20**	
n [2]	**18**	**18**	
MMRM: Least Squares Mean [SE] (95% CI)	**22.48 [20.26] (-18.20, 63.17)**	**9.49 [20.56] (-31.80, 50.78)**	
MMRM: Least Squares Mean Difference [SE] (95% CI)	**12.99 [28.32] (-43.90, 69.87)**		
MMRM: P-value	**0.65**		
Corrected Hedges' g (95% CI)	**0.147 (-0.508, 0.801)**		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	**0.39**		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

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Table 2.7324: Analysis of MPN-SAF Mean Questionnaire Item #24 Score and Change from Baseline

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
BFI0106 - Interfered Walking Past 24 Hours at Baseline		
n	50	29
Mean (SD)	4.0 (3.20)	4.9 (3.02)
Median	3.0	5.0
Q1, Q3	2.0, 7.0	2.0, 7.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
BFI0106 - Interfered Walking Past 24 Hours at Week 4		
n	60	31
Mean (SD)	3.8 (2.78)	4.7 (2.90)
Median	4.0	4.0
Q1, Q3	1.0, 6.0	3.0, 7.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in Interfered Walking Past 24 Hours at Week 4 from Baseline		
n	45	26
Mean (SD)	0.2 (2.71)	-0.6 (2.47)
Median	0.0	-0.5
Q1, Q3	-2.0, 2.0	-2.0, 1.0
Min, Max	-5.0, 7.0	-6.0, 5.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.

MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).

MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18), Visit and Treatment by Visit interaction as covariates.

[1] Number of subjects with analysable data for one or more time points.

[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7324: Analysis of MPN-SAF Mean Questionnaire Item #24 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	47	27	
n [2]	45	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.16 [0.34] (-0.53, 0.85)	-0.21 [0.42] (-1.05, 0.63)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.37 [0.54] (-0.71, 1.45)		
MMRM: P-value	0.49		
Corrected Hedges' g (95% CI)	0.163 (-0.320, 0.647)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.14		
Percent Change in Interfered Walking Past 24 Hours at Week 4 from Baseline			
n	38	23	
Mean (SD)	11.9 (97.74)	5.6 (75.45)	
Median	-15.6	-14.3	
Q1, Q3	-40.0, 40.0	-37.5, 40.0	
Min, Max	-100.0, 400.0	-100.0, 200.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	39	23	
n [2]	38	23	
MMRM: Least Squares Mean [SE] (95% CI)	15.61 [13.81] (-12.06, 43.28)	10.45 [16.85] (-23.31, 44.21)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	5.16 [21.71] (-38.33, 48.64)		
MMRM: P-value	0.81		
Corrected Hedges' g (95% CI)	0.061 (-0.457, 0.579)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.42		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.7324: Analysis of MPN-SAF Mean Questionnaire Item #24 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
BFI0106 - Interfered Walking Past 24 Hours at Week 8		
n	57	27
Mean (SD)	4.0 (3.01)	4.7 (2.33)
Median	4.0	4.0
Q1, Q3	1.0, 7.0	3.0, 7.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	86%	69%
Number of Subjects in Risk	61	36
Return Rate in Risk (%)	93%	75%
Change in Interfered Walking Past 24 Hours at Week 8 from Baseline		
n	44	24
Mean (SD)	0.5 (2.91)	-0.3 (2.46)
Median	0.0	0.0
Q1, Q3	-0.5, 2.0	-2.0, 1.5
Min, Max	-7.0, 6.0	-6.0, 6.0
Difference in Change from Baseline at Week 8		
n [1]	47	27
n [2]	44	24
MMRM: Least Squares Mean [SE] (95% CI)	0.42 [0.37] (-0.31, 1.15)	0.09 [0.46] (-0.83, 1.01)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.33 [0.59] (-0.84, 1.50)	
MMRM: P-value	0.57	
Corrected Hedges' g (95% CI)	0.138 (-0.360, 0.636)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.33	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

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Table 2.7324: Analysis of MPN-SAF Mean Questionnaire Item #24 Score and Change from Baseline

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in Interfered Walking Past 24 Hours at Week 8 from Baseline			
n	37	21	
Mean (SD)	36.9 (97.02)	5.9 (62.69)	
Median	0.0	0.0	
Q1, Q3	-22.2, 75.0	-37.5, 11.1	
Min, Max	-100.0, 300.0	-66.7, 200.0	
Difference in Percent Change from Baseline at Week 8			
n [1]	39	23	
n [2]	37	21	
MMRM: Least Squares Mean [SE] (95% CI)	40.08 [12.50] (15.03, 65.13)		12.93 [15.49] (-18.11, 43.97)
MMRM: Least Squares Mean Difference [SE] (95% CI)	27.15 [19.79] (-12.50, 66.80)		
MMRM: P-value	0.18		
Corrected Hedges' g (95% CI)	0.360 (-0.179, 0.900)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.15		
BFI0106 - Interfered Walking Past 24 Hours at Week 12			
n	51	30	
Mean (SD)	3.7 (2.88)	4.6 (2.81)	
Median	3.0	4.0	
Q1, Q3	1.0, 6.0	2.0, 7.0	
Min, Max	0.0, 9.0	0.0, 10.0	
Return Rate (%)	77%	77%	
Number of Subjects in Risk	59	33	
Return Rate in Risk (%)	86%	91%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7324: Analysis of MPN-SAF Mean Questionnaire Item #24 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Interfered Walking Past 24 Hours at Week 12 from Baseline		
n	37	26
Mean (SD)	0.2 (2.24)	-0.2 (2.11)
Median	0.0	0.0
Q1, Q3	0.0, 1.0	-2.0, 1.0
Min, Max	-6.0, 6.0	-5.0, 5.0
Difference in Change from Baseline at Week 12		
n [1]	47	27
n [2]	37	26
MMRM: Least Squares Mean [SE] (95% CI)	0.15 [0.35] (-0.55, 0.85)	0.13 [0.40] (-0.66, 0.92)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.02 [0.53] (-1.03, 1.07)	
MMRM: P-value	0.97	
Corrected Hedges' g (95% CI)	0.011 (-0.491, 0.512)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.71	
Percent Change in Interfered Walking Past 24 Hours at Week 12 from Baseline		
n	30	22
Mean (SD)	4.6 (52.29)	-4.9 (43.47)
Median	0.0	0.0
Q1, Q3	-22.2, 33.3	-25.0, 0.0
Min, Max	-100.0, 100.0	-100.0, 100.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7324: Analysis of MPN-SAF Mean Questionnaire Item #24 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 12			
n [1]	39	23	
n [2]	30	22	
MMRM: Least Squares Mean [SE] (95% CI)	5.11 [9.97] (-14.86, 25.08)		1.22 [10.67] (-20.14, 22.59)
MMRM: Least Squares Mean Difference [SE] (95% CI)	3.89 [14.44] (-25.03, 32.81)		
MMRM: P-value	0.79		
Corrected Hedges' g (95% CI)	0.073 (-0.478, 0.623)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.55		
BFI0106 - Interfered Walking Past 24 Hours at Week 16			
n	48	30	
Mean (SD)	3.4 (2.82)	4.7 (3.04)	
Median	3.0	5.0	
Q1, Q3	1.0, 5.0	3.0, 8.0	
Min, Max	0.0, 9.0	0.0, 10.0	
Return Rate (%)	73%	77%	
Number of Subjects in Risk	56	33	
Return Rate in Risk (%)	86%	91%	
Change in Interfered Walking Past 24 Hours at Week 16 from Baseline			
n	36	26	
Mean (SD)	-0.3 (2.44)	0.3 (2.30)	
Median	0.0	0.0	
Q1, Q3	-2.0, 1.0	-1.0, 2.0	
Min, Max	-5.0, 6.0	-4.0, 5.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn24-rt.pdf 24AUG2023:17:02

Table 2.7324: Analysis of MPN-SAF Mean Questionnaire Item #24 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	47	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.18 [0.36] (-0.90, 0.54)	0.64 [0.41] (-0.18, 1.45)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.81 [0.54] (-1.89, 0.27)		
MMRM: P-value	0.14		
Corrected Hedges' g (95% CI)	-0.376 (-0.885, 0.133)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.16		
Percent Change in Interfered Walking Past 24 Hours at Week 16 from Baseline			
n	30	22	
Mean (SD)	-6.6 (59.54)	6.6 (66.63)	
Median	-11.8	0.0	
Q1, Q3	-44.4, 16.7	-20.0, 28.6	
Min, Max	-100.0, 150.0	-100.0, 200.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	39	23	
n [2]	30	22	
MMRM: Least Squares Mean [SE] (95% CI)	1.80 [12.26] (-22.77, 26.37)	11.55 [13.70] (-15.89, 38.99)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-9.75 [18.24] (-46.29, 26.80)		
MMRM: P-value	0.60		
Corrected Hedges' g (95% CI)	-0.146 (-0.696, 0.405)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.25		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7324: Analysis of MPN-SAF Mean Questionnaire Item #24 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
BFI0106 - Interfered Walking Past 24 Hours at Week 20		
n	44	29
Mean (SD)	3.2 (2.41)	4.8 (2.88)
Median	3.5	5.0
Q1, Q3	1.0, 5.0	3.0, 7.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	67%	74%
Number of Subjects in Risk	51	32
Return Rate in Risk (%)	86%	91%
Change in Interfered Walking Past 24 Hours at Week 20 from Baseline		
n	32	24
Mean (SD)	-0.3 (2.82)	0.2 (1.86)
Median	0.0	0.0
Q1, Q3	-2.0, 1.5	-0.5, 1.0
Min, Max	-7.0, 5.0	-4.0, 4.0
Difference in Change from Baseline at Week 20		
n [1]	47	27
n [2]	32	24
MMRM: Least Squares Mean [SE] (95% CI)	-0.13 [0.36] (-0.85, 0.59)	0.48 [0.40] (-0.31, 1.28)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.61 [0.53] (-1.68, 0.45)	
MMRM: P-value	0.26	
Corrected Hedges' g (95% CI)	-0.302 (-0.834, 0.230)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.27	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn24-rt.pdf 24AUG2023:17:02

Table 2.7324: Analysis of MPN-SAF Mean Questionnaire Item #24 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in Interfered Walking Past 24 Hours at Week 20 from Baseline			
n	26	20	
Mean (SD)	22.6 (113.18)	-1.3 (37.85)	
Median	-13.9	0.0	
Q1, Q3	-33.3, 33.3	-22.6, 15.6	
Min, Max	-100.0, 400.0	-100.0, 66.7	
Difference in Percent Change from Baseline at Week 20			
n [1]	39	23	
n [2]	26	20	
MMRM: Least Squares Mean [SE] (95% CI)	27.41 [16.17] (-4.99, 59.80)	9.15 [18.27] (-27.44, 45.74)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	18.25 [24.30] (-30.43, 66.93)		
MMRM: P-value	0.46		
Corrected Hedges' g (95% CI)	0.218 (-0.366, 0.803)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.36		
BFI0106 - Interfered Walking Past 24 Hours at Week 24			
n	41	29	
Mean (SD)	3.5 (2.92)	5.0 (3.21)	
Median	3.0	5.0	
Q1, Q3	1.0, 6.0	2.0, 8.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	62%	74%	
Number of Subjects in Risk	48	31	
Return Rate in Risk (%)	85%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7324: Analysis of MPN-SAF Mean Questionnaire Item #24 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Interfered Walking Past 24 Hours at Week 24 from Baseline		
n	27	23
Mean (SD)	0.0 (2.94)	0.3 (1.97)
Median	0.0	0.0
Q1, Q3	-1.0, 1.0	-1.0, 2.0
Min, Max	-7.0, 6.0	-3.0, 5.0
Difference in Change from Baseline at Week 24		
n [1]	47	27
n [2]	27	23
MMRM: Least Squares Mean [SE] (95% CI)	0.01 [0.42] (-0.83, 0.85)	0.79 [0.46] (-0.13, 1.71)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.78 [0.62] (-2.02, 0.46)	
MMRM: P-value	0.21	
Corrected Hedges' g (95% CI)	-0.349 (-0.910, 0.211)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.62	
Percent Change in Interfered Walking Past 24 Hours at Week 24 from Baseline		
n	21	19
Mean (SD)	21.2 (84.80)	-5.5 (46.16)
Median	0.0	0.0
Q1, Q3	-20.0, 50.0	-20.0, 20.0
Min, Max	-100.0, 200.0	-100.0, 100.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7324: Analysis of MPN-SAF Mean Questionnaire Item #24 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	39	23	
n [2]	21	19	
MMRM: Least Squares Mean [SE] (95% CI)	26.59 [14.18] (-1.82, 55.00)	10.28 [15.41] (-20.58, 41.14)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	16.31 [20.82] (-25.40, 58.01)		
MMRM: P-value	0.44		
Corrected Hedges' g (95% CI)	0.242 (-0.381, 0.865)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.75		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

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Table 2.7325: Analysis of MPN-SAF Mean Questionnaire Item #25 Score and Change from Baseline

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
BFI0107 - Interfered Work Past 24 Hours at Baseline		
n	50	29
Mean (SD)	4.0 (2.82)	4.2 (3.24)
Median	4.0	4.0
Q1, Q3	2.0, 7.0	1.0, 6.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
BFI0107 - Interfered Work Past 24 Hours at Week 4		
n	60	31
Mean (SD)	4.3 (3.08)	4.9 (2.98)
Median	4.0	5.0
Q1, Q3	2.0, 7.0	3.0, 8.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in Interfered Work Past 24 Hours at Week 4 from Baseline		
n	45	26
Mean (SD)	0.9 (2.83)	0.6 (2.34)
Median	1.0	0.0
Q1, Q3	0.0, 2.0	-1.0, 2.0
Min, Max	-4.0, 8.0	-4.0, 6.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7325: Analysis of MPN-SAF Mean Questionnaire Item #25 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	47	27	
n [2]	45	26	
MMRM: Least Squares Mean [SE] (95% CI)	1.05 [0.37] (0.32, 1.78)		0.58 [0.43] (-0.29, 1.45)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.47 [0.57] (-0.66, 1.60)		
MMRM: P-value	0.41		
Corrected Hedges' g (95% CI)	0.194 (-0.290, 0.678)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.34		
Percent Change in Interfered Work Past 24 Hours at Week 4 from Baseline			
n	40	20	
Mean (SD)	30.0 (87.79)	44.8 (147.96)	
Median	12.7	0.0	
Q1, Q3	-19.6, 63.3	-21.1, 50.0	
Min, Max	-100.0, 350.0	-100.0, 600.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	41	21	
n [2]	40	20	
MMRM: Least Squares Mean [SE] (95% CI)	27.15 [17.79] (-8.49, 62.79)		51.46 [21.80] (7.79, 95.12)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-24.30 [28.39] (-81.18, 32.57)		
MMRM: P-value	0.40		
Corrected Hedges' g (95% CI)	-0.222 (-0.761, 0.316)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.44		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7325: Analysis of MPN-SAF Mean Questionnaire Item #25 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
BFI0107 - Interfered Work Past 24 Hours at Week 8			
n	57	27	
Mean (SD)	4.3 (3.07)	4.8 (2.42)	
Median	4.0	5.0	
Q1, Q3	2.0, 7.0	3.0, 7.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	86%	69%	
Number of Subjects in Risk	61	36	
Return Rate in Risk (%)	93%	75%	
Change in Interfered Work Past 24 Hours at Week 8 from Baseline			
n	44	24	
Mean (SD)	0.9 (3.18)	0.4 (2.22)	
Median	0.0	0.0	
Q1, Q3	-1.0, 2.0	-1.0, 1.0	
Min, Max	-7.0, 10.0	-3.0, 6.0	
Difference in Change from Baseline at Week 8			
n [1]	47	27	
n [2]	44	24	
MMRM: Least Squares Mean [SE] (95% CI)	1.20 [0.40] (0.39, 2.00)	0.59 [0.49] (-0.39, 1.56)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.61 [0.63] (-0.65, 1.87)		
MMRM: P-value	0.34		
Corrected Hedges' g (95% CI)	0.234 (-0.265, 0.733)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.57		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn25-rt.pdf 24AUG2023:17:02

Table 2.7325: Analysis of MPN-SAF Mean Questionnaire Item #25 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Interfered Work Past 24 Hours at Week 8 from Baseline		
n	39	18
Mean (SD)	51.1 (124.26)	26.5 (143.89)
Median	0.0	0.0
Q1, Q3	-28.6, 100.0	-16.7, 0.0
Min, Max	-100.0, 400.0	-37.5, 600.0
Difference in Percent Change from Baseline at Week 8		
n [1]	41	21
n [2]	39	18
MMRM: Least Squares Mean [SE] (95% CI)	47.12 [19.84] (7.37, 86.87)	40.38 [25.31] (-10.33, 91.09)
MMRM: Least Squares Mean Difference [SE] (95% CI)	6.74 [32.28] (-57.92, 71.40)	
MMRM: P-value	0.84	
Corrected Hedges' g (95% CI)	0.056 (-0.503, 0.614)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.22	
BFI0107 - Interfered Work Past 24 Hours at Week 12		
n	51	30
Mean (SD)	3.9 (2.82)	4.8 (3.11)
Median	3.0	4.0
Q1, Q3	2.0, 6.0	3.0, 8.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	77%	77%
Number of Subjects in Risk	59	33
Return Rate in Risk (%)	86%	91%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7325: Analysis of MPN-SAF Mean Questionnaire Item #25 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Interfered Work Past 24 Hours at Week 12 from Baseline		
n	37	26
Mean (SD)	0.6 (2.83)	0.7 (2.43)
Median	0.0	0.0
Q1, Q3	-1.0, 2.0	-1.0, 2.0
Min, Max	-5.0, 10.0	-3.0, 6.0
Difference in Change from Baseline at Week 12		
n [1]	47	27
n [2]	37	26
MMRM: Least Squares Mean [SE] (95% CI)	0.73 [0.42] (-0.11, 1.56)	0.87 [0.49] (-0.10, 1.84)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.14 [0.64] (-1.42, 1.13)	
MMRM: P-value	0.82	
Corrected Hedges' g (95% CI)	-0.056 (-0.558, 0.446)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.75	
Percent Change in Interfered Work Past 24 Hours at Week 12 from Baseline		
n	32	20
Mean (SD)	34.0 (111.85)	46.6 (144.25)
Median	0.0	0.0
Q1, Q3	-33.3, 62.5	-22.5, 41.7
Min, Max	-100.0, 400.0	-60.0, 600.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7325: Analysis of MPN-SAF Mean Questionnaire Item #25 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 12			
n [1]	41	21	
n [2]	32	20	
MMRM: Least Squares Mean [SE] (95% CI)	35.20 [20.24] (-5.34, 75.74)		58.80 [24.69] (9.33, 108.27)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-23.60 [32.09] (-87.89, 40.69)		
MMRM: P-value	0.47		
Corrected Hedges' g (95% CI)	-0.206 (-0.766, 0.354)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.61		
BFI0107 - Interfered Work Past 24 Hours at Week 16			
n	48	30	
Mean (SD)	3.4 (2.74)	5.0 (2.94)	
Median	2.5	5.0	
Q1, Q3	1.0, 6.0	3.0, 8.0	
Min, Max	0.0, 9.0	0.0, 10.0	
Return Rate (%)	73%	77%	
Number of Subjects in Risk	56	33	
Return Rate in Risk (%)	86%	91%	
Change in Interfered Work Past 24 Hours at Week 16 from Baseline			
n	36	26	
Mean (SD)	-0.4 (2.43)	1.2 (2.31)	
Median	0.0	0.0	
Q1, Q3	-2.0, 1.0	0.0, 3.0	
Min, Max	-5.0, 4.0	-2.0, 7.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn25-rt.pdf 24AUG2023:17:02

Table 2.7325: Analysis of MPN-SAF Mean Questionnaire Item #25 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	47	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.34 [0.39] (-0.44, 1.13)	1.28 [0.44] (0.40, 2.17)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.94 [0.59] (-2.11, 0.24)		
MMRM: P-value	0.12		
Corrected Hedges' g (95% CI)	-0.400 (-0.909, 0.110)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.065		
Percent Change in Interfered Work Past 24 Hours at Week 16 from Baseline			
n	32	20	
Mean (SD)	7.0 (99.37)	66.0 (166.20)	
Median	0.0	0.0	
Q1, Q3	-56.3, 14.6	-11.8, 66.7	
Min, Max	-100.0, 300.0	-50.0, 700.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	41	21	
n [2]	32	20	
MMRM: Least Squares Mean [SE] (95% CI)	15.01 [21.04] (-27.14, 57.17)	78.43 [25.84] (26.67, 130.19)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-63.41 [33.47] (-130.47, 3.64)		
MMRM: P-value	0.063		
Corrected Hedges' g (95% CI)	-0.531 (-1.098, 0.037)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.16		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7325: Analysis of MPN-SAF Mean Questionnaire Item #25 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
BFI0107 - Interfered Work Past 24 Hours at Week 20		
n	44	29
Mean (SD)	3.4 (2.33)	4.8 (3.05)
Median	3.0	5.0
Q1, Q3	2.0, 5.0	3.0, 8.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	67%	74%
Number of Subjects in Risk	51	32
Return Rate in Risk (%)	86%	91%
Change in Interfered Work Past 24 Hours at Week 20 from Baseline		
n	32	24
Mean (SD)	-0.2 (2.74)	0.6 (2.43)
Median	0.0	0.0
Q1, Q3	-1.0, 2.0	-1.0, 1.5
Min, Max	-8.0, 4.0	-3.0, 7.0
Difference in Change from Baseline at Week 20		
n [1]	47	27
n [2]	32	24
MMRM: Least Squares Mean [SE] (95% CI)	0.58 [0.40] (-0.22, 1.38)	0.84 [0.45] (-0.07, 1.74)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.25 [0.60] (-1.46, 0.95)	
MMRM: P-value	0.68	
Corrected Hedges' g (95% CI)	-0.111 (-0.640, 0.419)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.66	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn25-rt.pdf 24AUG2023:17:02

Table 2.7325: Analysis of MPN-SAF Mean Questionnaire Item #25 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Interfered Work Past 24 Hours at Week 20 from Baseline		
n	28	19
Mean (SD)	26.5 (111.54)	46.6 (167.93)
Median	0.0	0.0
Q1, Q3	-29.2, 45.0	-20.0, 50.0
Min, Max	-100.0, 400.0	-50.0, 700.0
Difference in Percent Change from Baseline at Week 20		
n [1]	41	21
n [2]	28	19
MMRM: Least Squares Mean [SE] (95% CI)	34.38 [20.73] (-7.14, 75.90)	60.52 [25.69] (9.06, 111.98)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-26.14 [33.17] (-92.59, 40.31)	
MMRM: P-value	0.43	
Corrected Hedges' g (95% CI)	-0.232 (-0.817, 0.352)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.78	
BFI0107 - Interfered Work Past 24 Hours at Week 24		
n	41	29
Mean (SD)	3.6 (2.83)	5.2 (3.03)
Median	3.0	5.0
Q1, Q3	1.0, 5.0	2.0, 8.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	62%	74%
Number of Subjects in Risk	48	31
Return Rate in Risk (%)	85%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn25-rt.pdf 24AUG2023:17:02

Table 2.7325: Analysis of MPN-SAF Mean Questionnaire Item #25 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Interfered Work Past 24 Hours at Week 24 from Baseline		
n	27	23
Mean (SD)	0.0 (2.92)	1.0 (2.16)
Median	1.0	0.0
Q1, Q3	-1.0, 2.0	0.0, 3.0
Min, Max	-8.0, 5.0	-2.0, 6.0
Difference in Change from Baseline at Week 24		
n [1]	47	27
n [2]	27	23
MMRM: Least Squares Mean [SE] (95% CI)	0.50 [0.43] (-0.36, 1.36)	1.38 [0.47] (0.45, 2.32)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.88 [0.63] (-2.14, 0.38)	
MMRM: P-value	0.17	
Corrected Hedges' g (95% CI)	-0.389 (-0.950, 0.172)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.31	
Percent Change in Interfered Work Past 24 Hours at Week 24 from Baseline		
n	23	18
Mean (SD)	23.5 (99.06)	53.9 (135.99)
Median	14.3	0.0
Q1, Q3	-57.1, 66.7	-11.1, 50.0
Min, Max	-100.0, 300.0	-50.0, 500.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7325: Analysis of MPN-SAF Mean Questionnaire Item #25 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	41	21	
n [2]	23	18	
MMRM: Least Squares Mean [SE] (95% CI)	22.94 [18.86] (-14.84, 60.72)	70.22 [20.74] (28.67, 111.76)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-47.28 [28.18] (-103.73, 9.17)		
MMRM: P-value	0.099		
Corrected Hedges' g (95% CI)	-0.519 (-1.146, 0.108)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.50		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

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Table 2.7326: Analysis of MPN-SAF Mean Questionnaire Item #26 Score and Change from Baseline

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
BFI0108 - Interfered Relations Past 24 Hours at Baseline		
n	50	29
Mean (SD)	2.7 (2.75)	3.4 (2.92)
Median	2.0	2.0
Q1, Q3	0.0, 5.0	0.0, 6.0
Min, Max	0.0, 9.0	0.0, 9.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
BFI0108 - Interfered Relations Past 24 Hours at Week 4		
n	60	31
Mean (SD)	2.9 (2.58)	4.1 (3.06)
Median	2.0	4.0
Q1, Q3	1.0, 5.0	1.0, 7.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in Interfered Relations Past 24 Hours at Week 4 from Baseline		
n	45	26
Mean (SD)	0.7 (2.55)	0.8 (2.84)
Median	1.0	0.5
Q1, Q3	-1.0, 2.0	-1.0, 2.0
Min, Max	-7.0, 7.0	-4.0, 7.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.

MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).

MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18), Visit and Treatment by Visit interaction as covariates.

[1] Number of subjects with analysable data for one or more time points.

[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7326: Analysis of MPN-SAF Mean Questionnaire Item #26 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	47	27	
n [2]	45	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.87 [0.33] (0.20, 1.53)		1.07 [0.40] (0.27, 1.86)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.20 [0.52] (-1.23, 0.83)		
MMRM: P-value	0.70		
Corrected Hedges' g (95% CI)	-0.091 (-0.574, 0.392)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.91		
Percent Change in Interfered Relations Past 24 Hours at Week 4 from Baseline			
n	33	18	
Mean (SD)	43.6 (159.69)	4.6 (68.63)	
Median	0.0	0.0	
Q1, Q3	-33.3, 50.0	-50.0, 40.0	
Min, Max	-100.0, 600.0	-100.0, 150.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	34	19	
n [2]	33	18	
MMRM: Least Squares Mean [SE] (95% CI)	28.82 [23.20] (-17.86, 75.50)		15.14 [29.65] (-44.50, 74.79)
MMRM: Least Squares Mean Difference [SE] (95% CI)	13.67 [37.94] (-62.66, 90.01)		
MMRM: P-value	0.72		
Corrected Hedges' g (95% CI)	0.103 (-0.472, 0.678)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.47		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7326: Analysis of MPN-SAF Mean Questionnaire Item #26 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
BFI0108 - Interfered Relations Past 24 Hours at Week 8			
n	57	27	
Mean (SD)	2.9 (2.61)	3.3 (2.58)	
Median	2.0	3.0	
Q1, Q3	0.0, 5.0	1.0, 6.0	
Min, Max	0.0, 8.0	0.0, 9.0	
Return Rate (%)	86%	69%	
Number of Subjects in Risk	61	36	
Return Rate in Risk (%)	93%	75%	
Change in Interfered Relations Past 24 Hours at Week 8 from Baseline			
n	44	24	
Mean (SD)	0.8 (2.58)	0.1 (2.60)	
Median	0.5	0.0	
Q1, Q3	-1.0, 2.0	-1.0, 2.0	
Min, Max	-7.0, 7.0	-6.0, 5.0	
Difference in Change from Baseline at Week 8			
n [1]	47	27	
n [2]	44	24	
MMRM: Least Squares Mean [SE] (95% CI)	0.91 [0.36] (0.19, 1.63)	0.60 [0.45] (-0.29, 1.49)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.31 [0.57] (-0.82, 1.44)		
MMRM: P-value	0.59		
Corrected Hedges' g (95% CI)	0.132 (-0.366, 0.629)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.77		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn26-rt.pdf 24AUG2023:17:02

Table 2.7326: Analysis of MPN-SAF Mean Questionnaire Item #26 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Interfered Relations Past 24 Hours at Week 8 from Baseline		
n	32	17
Mean (SD)	52.3 (178.65)	-19.4 (47.17)
Median	0.0	0.0
Q1, Q3	-41.7, 100.0	-50.0, 0.0
Min, Max	-100.0, 700.0	-100.0, 50.0
Difference in Percent Change from Baseline at Week 8		
n [1]	34	19
n [2]	32	17
MMRM: Least Squares Mean [SE] (95% CI)	34.34 [26.56] (-19.08, 87.76)	-12.02 [34.57] (-81.57, 57.53)
MMRM: Least Squares Mean Difference [SE] (95% CI)	46.36 [43.68] (-41.52, 134.24)	
MMRM: P-value	0.29	
Corrected Hedges' g (95% CI)	0.309 (-0.282, 0.900)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.26	
BFI0108 - Interfered Relations Past 24 Hours at Week 12		
n	51	30
Mean (SD)	2.8 (2.79)	3.2 (2.75)
Median	2.0	3.0
Q1, Q3	0.0, 5.0	0.0, 5.0
Min, Max	0.0, 8.0	0.0, 10.0
Return Rate (%)	77%	77%
Number of Subjects in Risk	59	33
Return Rate in Risk (%)	86%	91%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7326: Analysis of MPN-SAF Mean Questionnaire Item #26 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Interfered Relations Past 24 Hours at Week 12 from Baseline		
n	37	26
Mean (SD)	0.7 (2.72)	0.1 (2.02)
Median	1.0	0.0
Q1, Q3	-1.0, 2.0	-2.0, 1.0
Min, Max	-5.0, 8.0	-3.0, 5.0
Difference in Change from Baseline at Week 12		
n [1]	47	27
n [2]	37	26
MMRM: Least Squares Mean [SE] (95% CI)	0.73 [0.39] (-0.05, 1.51)	0.40 [0.45] (-0.50, 1.30)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.33 [0.59] (-0.85, 1.51)	
MMRM: P-value	0.58	
Corrected Hedges' g (95% CI)	0.140 (-0.362, 0.643)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.45	
Percent Change in Interfered Relations Past 24 Hours at Week 12 from Baseline		
n	26	18
Mean (SD)	62.9 (176.94)	-12.7 (63.14)
Median	8.3	-14.3
Q1, Q3	-50.0, 100.0	-50.0, 11.1
Min, Max	-100.0, 600.0	-100.0, 150.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7326: Analysis of MPN-SAF Mean Questionnaire Item #26 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 12			
n [1]	34	19	
n [2]	26	18	
MMRM: Least Squares Mean [SE] (95% CI)	34.56 [25.60] (-16.93, 86.05)	-2.36 [31.37] (-65.47, 60.76)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	36.92 [40.65] (-44.85, 118.70)		
MMRM: P-value	0.37		
Corrected Hedges' g (95% CI)	0.276 (-0.328, 0.879)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.29		
BFI0108 - Interfered Relations Past 24 Hours at Week 16			
n	48	30	
Mean (SD)	2.3 (2.51)	3.2 (3.03)	
Median	2.0	3.0	
Q1, Q3	0.0, 4.0	0.0, 6.0	
Min, Max	0.0, 9.0	0.0, 10.0	
Return Rate (%)	73%	77%	
Number of Subjects in Risk	56	33	
Return Rate in Risk (%)	86%	91%	
Change in Interfered Relations Past 24 Hours at Week 16 from Baseline			
n	36	26	
Mean (SD)	0.1 (2.67)	0.3 (2.94)	
Median	0.0	0.0	
Q1, Q3	-2.0, 1.5	-1.0, 1.0	
Min, Max	-5.0, 7.0	-7.0, 8.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn26-rt.pdf 24AUG2023:17:02

Table 2.7326: Analysis of MPN-SAF Mean Questionnaire Item #26 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	47	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.48 [0.44] (-0.39, 1.35)	0.67 [0.51] (-0.36, 1.69)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.19 [0.67] (-1.52, 1.15)		
MMRM: P-value	0.78		
Corrected Hedges' g (95% CI)	-0.071 (-0.575, 0.434)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.81		
Percent Change in Interfered Relations Past 24 Hours at Week 16 from Baseline			
n	25	18	
Mean (SD)	26.3 (174.61)	-3.3 (81.60)	
Median	-33.3	0.0	
Q1, Q3	-100.0, 33.3	-40.0, 11.1	
Min, Max	-100.0, 700.0	-100.0, 250.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	34	19	
n [2]	25	18	
MMRM: Least Squares Mean [SE] (95% CI)	16.49 [27.74] (-39.32, 72.30)	7.12 [34.99] (-63.27, 77.51)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	9.37 [44.79] (-80.75, 99.48)		
MMRM: P-value	0.84		
Corrected Hedges' g (95% CI)	0.064 (-0.542, 0.670)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.74		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7326: Analysis of MPN-SAF Mean Questionnaire Item #26 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
BFI0108 - Interfered Relations Past 24 Hours at Week 20			
n	44	29	
Mean (SD)	2.0 (2.02)	3.2 (3.02)	
Median	2.0	2.0	
Q1, Q3	0.0, 3.0	1.0, 5.0	
Min, Max	0.0, 8.0	0.0, 10.0	
Return Rate (%)	67%	74%	
Number of Subjects in Risk	51	32	
Return Rate in Risk (%)	86%	91%	
Change in Interfered Relations Past 24 Hours at Week 20 from Baseline			
n	32	24	
Mean (SD)	-0.1 (2.73)	0.1 (2.73)	
Median	0.0	0.0	
Q1, Q3	-2.0, 2.0	-1.0, 1.0	
Min, Max	-7.0, 5.0	-6.0, 7.0	
Difference in Change from Baseline at Week 20			
n [1]	47	27	
n [2]	32	24	
MMRM: Least Squares Mean [SE] (95% CI)	0.38 [0.42] (-0.46, 1.21)	0.47 [0.47] (-0.46, 1.41)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.10 [0.63] (-1.34, 1.15)		
MMRM: P-value	0.88		
Corrected Hedges' g (95% CI)	-0.041 (-0.570, 0.489)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.78		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7326: Analysis of MPN-SAF Mean Questionnaire Item #26 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Interfered Relations Past 24 Hours at Week 20 from Baseline		
n	21	16
Mean (SD)	23.2 (130.35)	9.9 (102.43)
Median	-14.3	0.0
Q1, Q3	-77.8, 100.0	-45.0, 15.6
Min, Max	-100.0, 300.0	-85.7, 350.0
Difference in Percent Change from Baseline at Week 20		
n [1]	34	19
n [2]	21	16
MMRM: Least Squares Mean [SE] (95% CI)	13.22 [22.81] (-32.67, 59.10)	34.36 [25.85] (-17.65, 86.37)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-21.14 [34.72] (-90.99, 48.70)	
MMRM: P-value	0.55	
Corrected Hedges' g (95% CI)	-0.199 (-0.851, 0.453)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.26	
BFI0108 - Interfered Relations Past 24 Hours at Week 24		
n	41	29
Mean (SD)	2.2 (2.22)	3.6 (2.86)
Median	2.0	3.0
Q1, Q3	0.0, 3.0	2.0, 6.0
Min, Max	0.0, 8.0	0.0, 10.0
Return Rate (%)	62%	74%
Number of Subjects in Risk	48	31
Return Rate in Risk (%)	85%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn26-rt.pdf 24AUG2023:17:02

Table 2.7326: Analysis of MPN-SAF Mean Questionnaire Item #26 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Interfered Relations Past 24 Hours at Week 24 from Baseline		
n	27	23
Mean (SD)	0.0 (2.50)	0.3 (1.96)
Median	0.0	0.0
Q1, Q3	-1.0, 2.0	-1.0, 1.0
Min, Max	-8.0, 4.0	-3.0, 5.0
Difference in Change from Baseline at Week 24		
n [1]	47	27
n [2]	27	23
MMRM: Least Squares Mean [SE] (95% CI)	0.26 [0.37] (-0.48, 0.99)	0.71 [0.40] (-0.09, 1.50)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.45 [0.54] (-1.53, 0.63)	
MMRM: P-value	0.41	
Corrected Hedges' g (95% CI)	-0.232 (-0.790, 0.326)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.80	
Percent Change in Interfered Relations Past 24 Hours at Week 24 from Baseline		
n	17	15
Mean (SD)	13.3 (117.42)	-3.8 (37.69)
Median	0.0	0.0
Q1, Q3	-50.0, 33.3	-42.9, 20.0
Min, Max	-100.0, 400.0	-50.0, 60.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7326: Analysis of MPN-SAF Mean Questionnaire Item #26 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	**34**	**19**	
n [2]	**17**	**15**	
MMRM: Least Squares Mean [SE] (95% CI)	**-3.21 [20.69] (-44.84, 38.41)**	**7.17 [23.60] (-40.31, 54.65)**	
MMRM: Least Squares Mean Difference [SE] (95% CI)	**-10.39 [31.71] (-74.17, 53.40)**		
MMRM: P-value	**0.74**		
Corrected Hedges' g (95% CI)	**-0.115 (-0.810, 0.580)**		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	**0.46**		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

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Table 2.7327: Analysis of MPN-SAF Mean Questionnaire Item #27 Score and Change from Baseline

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
BFI0109 - Interfered Enjoyment Past 24 Hours at Baseline		
n	50	29
Mean (SD)	3.6 (3.25)	4.2 (2.92)
Median	3.0	4.0
Q1, Q3	1.0, 7.0	2.0, 7.0
Min, Max	0.0, 10.0	0.0, 9.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
BFI0109 - Interfered Enjoyment Past 24 Hours at Week 4		
n	60	31
Mean (SD)	3.6 (3.04)	4.5 (3.28)
Median	3.0	5.0
Q1, Q3	1.0, 6.0	2.0, 8.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in Interfered Enjoyment Past 24 Hours at Week 4 from Baseline		
n	45	26
Mean (SD)	0.5 (2.60)	0.2 (2.94)
Median	0.0	0.0
Q1, Q3	-1.0, 2.0	-1.0, 1.0
Min, Max	-6.0, 7.0	-5.0, 7.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7327: Analysis of MPN-SAF Mean Questionnaire Item #27 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	47	27	
n [2]	45	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.65 [0.38] (-0.11, 1.41)	0.42 [0.46] (-0.49, 1.33)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.23 [0.59] (-0.95, 1.41)		
MMRM: P-value	0.70		
Corrected Hedges' g (95% CI)	0.092 (-0.391, 0.575)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.18		
Percent Change in Interfered Enjoyment Past 24 Hours at Week 4 from Baseline			
n	35	22	
Mean (SD)	44.0 (147.48)	17.9 (113.25)	
Median	0.0	0.0	
Q1, Q3	-25.0, 50.0	-25.0, 20.0	
Min, Max	-100.0, 600.0	-100.0, 350.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	36	23	
n [2]	35	22	
MMRM: Least Squares Mean [SE] (95% CI)	43.78 [23.45] (-3.26, 90.82)	19.64 [26.57] (-33.65, 72.92)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	24.14 [35.34] (-46.73, 95.02)		
MMRM: P-value	0.50		
Corrected Hedges' g (95% CI)	0.178 (-0.356, 0.713)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.43		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7327: Analysis of MPN-SAF Mean Questionnaire Item #27 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
BFI0109 - Interfered Enjoyment Past 24 Hours at Week 8			
n	57	27	
Mean (SD)	3.8 (3.04)	3.9 (2.77)	
Median	3.0	4.0	
Q1, Q3	1.0, 7.0	2.0, 6.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	86%	69%	
Number of Subjects in Risk	61	36	
Return Rate in Risk (%)	93%	75%	
Change in Interfered Enjoyment Past 24 Hours at Week 8 from Baseline			
n	44	24	
Mean (SD)	0.7 (3.14)	-0.1 (2.55)	
Median	0.0	0.0	
Q1, Q3	-1.0, 2.0	-2.0, 1.0	
Min, Max	-7.0, 7.0	-5.0, 6.0	
Difference in Change from Baseline at Week 8			
n [1]	47	27	
n [2]	44	24	
MMRM: Least Squares Mean [SE] (95% CI)	0.87 [0.41] (0.05, 1.69)	0.29 [0.51] (-0.73, 1.30)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.58 [0.65] (-0.71, 1.88)		
MMRM: P-value	0.37		
Corrected Hedges' g (95% CI)	0.217 (-0.282, 0.716)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.45		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7327: Analysis of MPN-SAF Mean Questionnaire Item #27 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Interfered Enjoyment Past 24 Hours at Week 8 from Baseline		
n	34	20
Mean (SD)	95.3 (206.11)	10.3 (94.77)
Median	0.0	-6.3
Q1, Q3	-33.3, 100.0	-34.3, 30.6
Min, Max	-100.0, 700.0	-100.0, 300.0
Difference in Percent Change from Baseline at Week 8		
n [1]	36	23
n [2]	34	20
MMRM: Least Squares Mean [SE] (95% CI)	92.37 [27.31] (37.60, 147.14)	20.38 [32.40] (-44.62, 85.37)
MMRM: Least Squares Mean Difference [SE] (95% CI)	71.99 [42.22] (-12.69, 156.67)	
MMRM: P-value	0.094	
Corrected Hedges' g (95% CI)	0.460 (-0.099, 1.019)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.18	
BFI0109 - Interfered Enjoyment Past 24 Hours at Week 12		
n	51	30
Mean (SD)	3.5 (3.13)	4.3 (2.99)
Median	3.0	4.0
Q1, Q3	0.0, 6.0	2.0, 7.0
Min, Max	0.0, 10.0	0.0, 10.0
Return Rate (%)	77%	77%
Number of Subjects in Risk	59	33
Return Rate in Risk (%)	86%	91%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7327: Analysis of MPN-SAF Mean Questionnaire Item #27 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Interfered Enjoyment Past 24 Hours at Week 12 from Baseline			
n	37	26	
Mean (SD)	0.8 (3.44)	0.3 (2.43)	
Median	0.0	0.0	
Q1, Q3	-1.0, 3.0	-1.0, 2.0	
Min, Max	-5.0, 10.0	-5.0, 5.0	
Difference in Change from Baseline at Week 12			
n [1]	47	27	
n [2]	37	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.70 [0.46] (-0.23, 1.63)	0.55 [0.54] (-0.53, 1.63)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.15 [0.71] (-1.27, 1.56)		
MMRM: P-value	0.84		
Corrected Hedges' g (95% CI)	0.051 (-0.450, 0.553)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.86		
Percent Change in Interfered Enjoyment Past 24 Hours at Week 12 from Baseline			
n	28	22	
Mean (SD)	106.0 (239.95)	16.8 (79.49)	
Median	0.0	0.0	
Q1, Q3	-50.0, 141.7	-20.0, 50.0	
Min, Max	-100.0, 900.0	-100.0, 200.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7327: Analysis of MPN-SAF Mean Questionnaire Item #27 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 12			
n [1]	36	23	
n [2]	28	22	
MMRM: Least Squares Mean [SE] (95% CI)	92.53 [30.09] (32.18, 152.88)	19.24 [34.29] (-49.53, 88.02)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	73.29 [45.48] (-17.94, 164.52)		
MMRM: P-value	0.11		
Corrected Hedges' g (95% CI)	0.451 (-0.114, 1.016)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.37		
BFI0109 - Interfered Enjoyment Past 24 Hours at Week 16			
n	48	30	
Mean (SD)	2.9 (2.79)	4.0 (3.07)	
Median	2.0	4.0	
Q1, Q3	0.5, 5.0	1.0, 6.0	
Min, Max	0.0, 10.0	0.0, 10.0	
Return Rate (%)	73%	77%	
Number of Subjects in Risk	56	33	
Return Rate in Risk (%)	86%	91%	
Change in Interfered Enjoyment Past 24 Hours at Week 16 from Baseline			
n	36	26	
Mean (SD)	-0.3 (2.97)	0.3 (2.77)	
Median	0.0	0.0	
Q1, Q3	-3.0, 1.0	-2.0, 2.0	
Min, Max	-6.0, 7.0	-4.0, 8.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7327: Analysis of MPN-SAF Mean Questionnaire Item #27 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	47	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.18 [0.45] (-0.73, 1.09)	0.59 [0.52] (-0.45, 1.62)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.41 [0.69] (-1.78, 0.96)		
MMRM: P-value	0.56		
Corrected Hedges' g (95% CI)	-0.149 (-0.654, 0.356)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.30		
Percent Change in Interfered Enjoyment Past 24 Hours at Week 16 from Baseline			
n	27	22	
Mean (SD)	50.1 (205.66)	22.1 (123.20)	
Median	-37.5	0.0	
Q1, Q3	-66.7, 16.7	-42.9, 20.0	
Min, Max	-100.0, 700.0	-100.0, 400.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	36	23	
n [2]	27	22	
MMRM: Least Squares Mean [SE] (95% CI)	44.94 [31.17] (-17.58, 107.45)	24.26 [33.83] (-43.60, 92.12)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	20.67 [45.85] (-71.29, 112.64)		
MMRM: P-value	0.65		
Corrected Hedges' g (95% CI)	0.127 (-0.437, 0.690)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.62		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7327: Analysis of MPN-SAF Mean Questionnaire Item #27 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
BFI0109 - Interfered Enjoyment Past 24 Hours at Week 20			
n	44	29	
Mean (SD)	2.8 (2.22)	4.1 (3.23)	
Median	2.0	4.0	
Q1, Q3	1.0, 4.0	1.0, 7.0	
Min, Max	0.0, 8.0	0.0, 10.0	
Return Rate (%)	67%	74%	
Number of Subjects in Risk	51	32	
Return Rate in Risk (%)	86%	91%	
Change in Interfered Enjoyment Past 24 Hours at Week 20 from Baseline			
n	32	24	
Mean (SD)	-0.1 (2.95)	0.0 (3.04)	
Median	0.0	0.0	
Q1, Q3	-2.0, 2.0	-1.0, 1.0	
Min, Max	-8.0, 5.0	-7.0, 8.0	
Difference in Change from Baseline at Week 20			
n [1]	47	27	
n [2]	32	24	
MMRM: Least Squares Mean [SE] (95% CI)	0.34 [0.45] (-0.56, 1.25)	0.40 [0.51] (-0.61, 1.42)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.06 [0.68] (-1.41, 1.29)		
MMRM: P-value	0.93		
Corrected Hedges' g (95% CI)	-0.024 (-0.554, 0.505)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.98		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn27-rt.pdf 24AUG2023:17:02

Table 2.7327: Analysis of MPN-SAF Mean Questionnaire Item #27 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Interfered Enjoyment Past 24 Hours at Week 20 from Baseline		
n	23	21
Mean (SD)	69.2 (171.79)	24.8 (121.93)
Median	0.0	0.0
Q1, Q3	-44.4, 200.0	-50.0, 14.3
Min, Max	-100.0, 500.0	-87.5, 400.0
Difference in Percent Change from Baseline at Week 20		
n [1]	36	23
n [2]	23	21
MMRM: Least Squares Mean [SE] (95% CI)	64.00 [27.34] (9.16, 118.84)	31.54 [27.05] (-22.71, 85.80)
MMRM: Least Squares Mean Difference [SE] (95% CI)	32.45 [38.12] (-44.00, 108.91)	
MMRM: P-value	0.40	
Corrected Hedges' g (95% CI)	0.249 (-0.344, 0.843)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.84	
BFI0109 - Interfered Enjoyment Past 24 Hours at Week 24		
n	41	29
Mean (SD)	3.0 (2.60)	4.3 (3.06)
Median	3.0	4.0
Q1, Q3	1.0, 5.0	2.0, 6.0
Min, Max	0.0, 9.0	0.0, 10.0
Return Rate (%)	62%	74%
Number of Subjects in Risk	48	31
Return Rate in Risk (%)	85%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7327: Analysis of MPN-SAF Mean Questionnaire Item #27 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Interfered Enjoyment Past 24 Hours at Week 24 from Baseline			
n	27	23	
Mean (SD)	0.3 (3.23)	0.0 (2.18)	
Median	0.0	0.0	
Q1, Q3	0.0, 2.0	-2.0, 2.0	
Min, Max	-8.0, 7.0	-5.0, 4.0	
Difference in Change from Baseline at Week 24			
n [1]	47	27	
n [2]	27	23	
MMRM: Least Squares Mean [SE] (95% CI)	0.55 [0.45] (-0.35, 1.45)	0.68 [0.49] (-0.29, 1.65)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.13 [0.66] (-1.44, 1.19)		
MMRM: P-value	0.85		
Corrected Hedges' g (95% CI)	-0.054 (-0.611, 0.502)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.51		
Percent Change in Interfered Enjoyment Past 24 Hours at Week 24 from Baseline			
n	18	20	
Mean (SD)	85.1 (187.21)	19.5 (83.28)	
Median	0.0	0.0	
Q1, Q3	-50.0, 200.0	-33.0, 39.3	
Min, Max	-100.0, 500.0	-100.0, 200.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7327: Analysis of MPN-SAF Mean Questionnaire Item #27 Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	**36**	**23**	
n [2]	**18**	**20**	
MMRM: Least Squares Mean [SE] (95% CI)	**54.49 [23.47] (7.42, 101.55)**	**35.02 [23.47] (-12.06, 82.10)**	
MMRM: Least Squares Mean Difference [SE] (95% CI)	**19.46 [32.86] (-46.44, 85.37)**		
MMRM: P-value	**0.56**		
Corrected Hedges' g (95% CI)	**0.186 (-0.452, 0.824)**		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	**0.58**		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MPN-SAF questionnaire encompasses the 9-item Brief Fatigue Inventory (BFI).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7201: Analysis of MPN-SAF Mean Symptom Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPNSAF - MPN-SAF at Baseline		
n	50	29
Mean (SD)	2.9 (1.94)	3.3 (1.94)
Median	2.5	3.0
Q1, Q3	1.3, 4.5	2.2, 4.8
Min, Max	0.0, 7.3	0.1, 7.9
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
MPNSAF - MPN-SAF at Week 4		
n	60	31
Mean (SD)	2.7 (1.79)	3.5 (2.02)
Median	2.3	3.6
Q1, Q3	1.3, 3.8	1.9, 4.6
Min, Max	0.1, 7.0	0.3, 8.9
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in MPN-SAF at Week 4 from Baseline		
n	45	26
Mean (SD)	0.1 (1.37)	0.1 (1.43)
Median	0.1	0.0
Q1, Q3	-0.8, 0.7	-0.9, 0.6
Min, Max	-2.3, 3.5	-2.2, 3.6

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7201: Analysis of MPN-SAF Mean Symptom Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	47	27	
n [2]	45	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.14 [0.20] (-0.26, 0.54)	0.24 [0.24] (-0.24, 0.72)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.10 [0.31] (-0.72, 0.52)		
MMRM: P-value	0.75		
Corrected Hedges' g (95% CI)	-0.077 (-0.560, 0.406)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.50		
Percent Change in MPN-SAF at Week 4 from Baseline			
n	44	26	
Mean (SD)	66.5 (295.86)	26.1 (81.93)	
Median	6.1	2.3	
Q1, Q3	-23.1, 38.3	-27.5, 31.6	
Min, Max	-85.7, 1900.0	-52.3, 300.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	46	27	
n [2]	44	26	
MMRM: Least Squares Mean [SE] (95% CI)	46.69 [38.81] (-30.78, 124.17)	31.48 [49.81] (-67.93, 130.90)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	15.21 [63.09] (-110.71, 141.13)		
MMRM: P-value	0.81		
Corrected Hedges' g (95% CI)	0.059 (-0.426, 0.544)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.68		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7201: Analysis of MPN-SAF Mean Symptom Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
MPNSAF - MPN-SAF at Week 8		
n	57	27
Mean (SD)	2.7 (1.72)	3.1 (1.64)
Median	2.4	3.0
Q1, Q3	1.5, 3.6	2.2, 3.9
Min, Max	0.0, 6.6	0.3, 8.3
Return Rate (%)	86%	69%
Number of Subjects in Risk	61	36
Return Rate in Risk (%)	93%	75%
Change in MPN-SAF at Week 8 from Baseline		
n	44	24
Mean (SD)	0.2 (1.38)	-0.2 (1.21)
Median	0.0	0.0
Q1, Q3	-0.7, 0.9	-0.7, 0.4
Min, Max	-2.7, 3.7	-2.9, 2.8
Difference in Change from Baseline at Week 8		
n [1]	47	27
n [2]	44	24
MMRM: Least Squares Mean [SE] (95% CI)	0.21 [0.20] (-0.19, 0.61)	0.08 [0.24] (-0.40, 0.55)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.13 [0.31] (-0.48, 0.75)	
MMRM: P-value	0.67	
Corrected Hedges' g (95% CI)	0.104 (-0.394, 0.601)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.83	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7201: Analysis of MPN-SAF Mean Symptom Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in MPN-SAF at Week 8 from Baseline		
n	43	24
Mean (SD)	35.8 (93.54)	24.2 (82.05)
Median	-1.5	0.0
Q1, Q3	-22.6, 58.8	-15.9, 23.2
Min, Max	-85.7, 338.1	-47.6, 314.3
Difference in Percent Change from Baseline at Week 8		
n [1]	46	27
n [2]	43	24
MMRM: Least Squares Mean [SE] (95% CI)	42.65 [14.29] (14.13, 71.17)	29.17 [16.38] (-3.52, 61.86)
MMRM: Least Squares Mean Difference [SE] (95% CI)	13.48 [21.47] (-29.37, 56.33)	
MMRM: P-value	0.53	
Corrected Hedges' g (95% CI)	0.149 (-0.351, 0.649)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.90	
MPNSAF - MPN-SAF at Week 12		
n	51	30
Mean (SD)	2.5 (1.67)	3.3 (1.97)
Median	2.3	2.9
Q1, Q3	1.4, 3.7	2.0, 4.2
Min, Max	0.0, 6.9	0.4, 9.0
Return Rate (%)	77%	77%
Number of Subjects in Risk	59	33
Return Rate in Risk (%)	86%	91%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7201: Analysis of MPN-SAF Mean Symptom Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in MPN-SAF at Week 12 from Baseline		
n	37	26
Mean (SD)	0.1 (1.42)	0.1 (1.03)
Median	0.5	0.2
Q1, Q3	-0.6, 1.0	-0.6, 0.7
Min, Max	-4.0, 3.0	-2.1, 1.6
Difference in Change from Baseline at Week 12		
n [1]	47	27
n [2]	37	26
MMRM: Least Squares Mean [SE] (95% CI)	0.11 [0.22] (-0.33, 0.55)	0.24 [0.25] (-0.26, 0.74)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.13 [0.33] (-0.79, 0.52)	
MMRM: P-value	0.69	
Corrected Hedges' g (95% CI)	-0.099 (-0.601, 0.403)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.99	
Percent Change in MPN-SAF at Week 12 from Baseline		
n	36	26
Mean (SD)	31.4 (93.12)	33.5 (108.71)
Median	15.8	7.0
Q1, Q3	-31.0, 63.0	-15.4, 26.7
Min, Max	-66.7, 381.0	-51.8, 450.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn-rt.pdf 24AUG2023:16:59

Table 2.7201: Analysis of MPN-SAF Mean Symptom Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 12			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	37.35 [15.83] (5.74, 68.95)		40.04 [17.71] (4.70, 75.38)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.69 [23.49] (-49.58, 44.19)		
MMRM: P-value	0.91		
Corrected Hedges' g (95% CI)	-0.029 (-0.533, 0.476)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.81		
MPNSAF - MPN-SAF at Week 16			
n	48	30	
Mean (SD)	2.3 (1.71)	3.2 (1.92)	
Median	1.9	2.9	
Q1, Q3	1.1, 3.4	1.9, 4.7	
Min, Max	0.0, 7.0	0.1, 8.4	
Return Rate (%)	73%	77%	
Number of Subjects in Risk	56	33	
Return Rate in Risk (%)	86%	91%	
Change in MPN-SAF at Week 16 from Baseline			
n	36	26	
Mean (SD)	-0.3 (1.40)	0.3 (1.19)	
Median	-0.1	0.1	
Q1, Q3	-1.2, 0.7	-0.4, 1.0	
Min, Max	-4.1, 2.0	-1.6, 3.7	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7201: Analysis of MPN-SAF Mean Symptom Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Change from Baseline at Week 16		
n [1]	47	27
n [2]	36	26
MMRM: Least Squares Mean [SE] (95% CI)	-0.07 [0.22] (-0.51, 0.36)	0.47 [0.25] (-0.02, 0.97)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.55 [0.33] (-1.20, 0.11)	
MMRM: P-value	0.100	
Corrected Hedges' g (95% CI)	-0.419 (-0.929, 0.091)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.093	
Percent Change in MPN-SAF at Week 16 from Baseline		
n	35	26
Mean (SD)	10.5 (78.84)	35.5 (82.31)
Median	-14.7	4.8
Q1, Q3	-40.7, 26.9	-18.2, 48.7
Min, Max	-87.3, 271.4	-40.9, 271.4
Difference in Percent Change from Baseline at Week 16		
n [1]	46	27
n [2]	35	26
MMRM: Least Squares Mean [SE] (95% CI)	23.83 [14.10] (-4.31, 51.97)	42.07 [15.25] (11.64, 72.50)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-18.24 [20.46] (-59.07, 22.60)	
MMRM: P-value	0.38	
Corrected Hedges' g (95% CI)	-0.222 (-0.731, 0.287)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.049	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7201: Analysis of MPN-SAF Mean Symptom Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
MPNSAF - MPN-SAF at Week 20			
n	44	29	
Mean (SD)	2.2 (1.39)	3.4 (2.18)	
Median	1.9	3.0	
Q1, Q3	1.3, 2.9	1.9, 4.6	
Min, Max	0.0, 6.3	0.0, 8.7	
Return Rate (%)	67%	74%	
Number of Subjects in Risk	51	32	
Return Rate in Risk (%)	86%	91%	
Change in MPN-SAF at Week 20 from Baseline			
n	32	24	
Mean (SD)	-0.2 (1.58)	0.2 (1.17)	
Median	-0.3	0.0	
Q1, Q3	-0.7, 0.9	-0.2, 0.6	
Min, Max	-4.1, 2.6	-2.5, 3.0	
Difference in Change from Baseline at Week 20			
n [1]	47	27	
n [2]	32	24	
MMRM: Least Squares Mean [SE] (95% CI)		0.06 [0.23] (-0.40, 0.53)	0.42 [0.27] (-0.11, 0.95)
MMRM: Least Squares Mean Difference [SE] (95% CI)		-0.35 [0.35] (-1.05, 0.35)	
MMRM: P-value	0.32		
Corrected Hedges' g (95% CI)	-0.266 (-0.797, 0.266)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.18		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7201: Analysis of MPN-SAF Mean Symptom Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in MPN-SAF at Week 20 from Baseline		
n	31	24
Mean (SD)	33.8 (141.59)	13.0 (61.40)
Median	-14.0	1.4
Q1, Q3	-40.9, 43.8	-8.1, 13.4
Min, Max	-81.0, 640.0	-100.0, 186.0
Difference in Percent Change from Baseline at Week 20		
n [1]	46	27
n [2]	31	24
MMRM: Least Squares Mean [SE] (95% CI)	30.30 [19.76] (-9.14, 69.73)	22.07 [22.92] (-23.68, 67.81)
MMRM: Least Squares Mean Difference [SE] (95% CI)	8.23 [30.02] (-51.70, 68.16)	
MMRM: P-value	0.78	
Corrected Hedges' g (95% CI)	0.073 (-0.460, 0.606)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.13	
MPNSAF - MPN-SAF at Week 24		
n	41	29
Mean (SD)	2.2 (1.51)	3.5 (2.22)
Median	1.9	3.4
Q1, Q3	1.3, 2.9	2.0, 5.0
Min, Max	0.1, 6.1	0.3, 8.5
Return Rate (%)	62%	74%
Number of Subjects in Risk	48	31
Return Rate in Risk (%)	85%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-mpn.sas V.03.05 Output file: t-chg-mpn-rt.pdf 24AUG2023:16:59

Table 2.7201: Analysis of MPN-SAF Mean Symptom Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in MPN-SAF at Week 24 from Baseline		
n	27	23
Mean (SD)	-0.2 (1.64)	0.2 (1.04)
Median	0.0	0.0
Q1, Q3	-0.6, 0.7	-0.4, 0.7
Min, Max	-4.4, 2.7	-1.6, 3.4
Difference in Change from Baseline at Week 24		
n [1]	47	27
n [2]	27	23
MMRM: Least Squares Mean [SE] (95% CI)	0.04 [0.25] (-0.45, 0.53)	0.60 [0.28] (0.04, 1.16)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.56 [0.37] (-1.30, 0.19)	
MMRM: P-value	0.14	
Corrected Hedges' g (95% CI)	-0.417 (-0.979, 0.145)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.22	
Percent Change in MPN-SAF at Week 24 from Baseline		
n	26	23
Mean (SD)	48.5 (214.35)	22.9 (64.92)
Median	1.2	0.0
Q1, Q3	-27.9, 34.1	-14.7, 27.0
Min, Max	-93.7, 1040.0	-30.8, 216.3

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7201: Analysis of MPN-SAF Mean Symptom Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	46	27	
n [2]	26	23	
MMRM: Least Squares Mean [SE] (95% CI)	27.69 [28.44] (-29.08, 84.45)		34.71 [34.88] (-34.91, 104.33)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-7.02 [44.83] (-96.51, 82.46)		
MMRM: P-value	0.88		
Corrected Hedges' g (95% CI)	-0.044 (-0.605, 0.517)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.33		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form 27-Item Questionnaire.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

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Table 2.7401: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #1 at Week 24

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N = 66)	BAT (N = 39)	Total (N = 105)
MPN0101 - Early Satiety at Week 24			
Responder, n(%)	8 (12.1%)	7 (17.9%)	15 (14.3%)
Unadjusted Inverse Relative Risk (95% CI)	1.48 (0.58, 3.77)		
p-value [1]	0.41		
Unadjusted Inverse Odds Ratio (95% CI)	1.59 (0.53, 4.78)		
p-value [1]	0.41		
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.20, 0.09)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.32 (0.53, 3.26)		
p-value [2]	0.55		
Non-Responder, n(%)	58 (87.9%)	32 (82.1%)	90 (85.7%)
Non-missing	19 (28.8%)	16 (41.0%)	35 (33.3%)
Missing	39 (59.1%)	16 (41.0%)	55 (52.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.7402: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #2 at Week 24
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N = 66)	BAT (N = 39)	Total (N = 105)
MPN0102 - Abdominal Pain at Week 24			
Responder, n(%)	7 (10.6%)	2 (5.1%)	9 (8.6%)
Unadjusted Inverse Relative Risk (95% CI)	0.48 (0.11, 2.21)		
p-value [1]	0.35		
Unadjusted Inverse Odds Ratio (95% CI)	0.46 (0.09, 2.31)		
p-value [1]	0.34		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.05, 0.16)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.42 (0.10, 1.76)		
p-value [2]	0.24		
Non-Responder, n(%)	59 (89.4%)	37 (94.9%)	96 (91.4%)
Non-missing	20 (30.3%)	21 (53.8%)	41 (39.0%)
Missing	39 (59.1%)	16 (41.0%)	55 (52.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

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Table 2.7403: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #3 at Week 24

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N = 66)	BAT (N = 39)	Total (N = 105)
MPN0103 - Abdominal Discomfort at Week 24			
Responder, n(%)	8 (12.1%)	4 (10.3%)	12 (11.4%)
Unadjusted Inverse Relative Risk (95% CI)	0.85 (0.27, 2.63)		
p-value [1]	0.77		
Unadjusted Inverse Odds Ratio (95% CI)	0.83 (0.23, 2.95)		
p-value [1]	0.77		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.10, 0.14)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.79 (0.27, 2.31)		
p-value [2]	0.66		
Non-Responder, n(%)	58 (87.9%)	35 (89.7%)	93 (88.6%)
Non-missing	19 (28.8%)	19 (48.7%)	38 (36.2%)
Missing	39 (59.1%)	16 (41.0%)	55 (52.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.7404: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #4 at Week 24

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N = 66)	BAT (N = 39)	Total (N = 105)
MPN0104 - Inactivity at Week 24			
Responder, n(%)	9 (13.6%)	3 (7.7%)	12 (11.4%)
Unadjusted Inverse Relative Risk (95% CI)	0.56 (0.16, 1.96)		
p-value [1]	0.37		
Unadjusted Inverse Odds Ratio (95% CI)	0.53 (0.13, 2.08)		
p-value [1]	0.36		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.06, 0.18)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.49 (0.15, 1.62)		
p-value [2]	0.24		
Non-Responder, n(%)	57 (86.4%)	36 (92.3%)	93 (88.6%)
Non-missing	18 (27.3%)	20 (51.3%)	38 (36.2%)
Missing	39 (59.1%)	16 (41.0%)	55 (52.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.7405: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #5 at Week 24

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N = 66)	BAT (N = 39)	Total (N = 105)
MPN0105 - Headaches at Week 24			
Responder, n(%)	3 (4.5%)	4 (10.3%)	7 (6.7%)
Unadjusted Inverse Relative Risk (95% CI)	2.26 (0.53, 9.56)		
p-value [1]	0.27		
Unadjusted Inverse Odds Ratio (95% CI)	2.40 (0.51, 11.34)		
p-value [1]	0.27		
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.16, 0.05)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.97 (0.52, 7.38)		
p-value [2]	0.32		
Non-Responder, n(%)	63 (95.5%)	35 (89.7%)	98 (93.3%)
Non-missing	24 (36.4%)	19 (48.7%)	43 (41.0%)
Missing	39 (59.1%)	16 (41.0%)	55 (52.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.7406: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #6 at Week 24

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N = 66)	BAT (N = 39)	Total (N = 105)
MPN0106 - Concentration at Week 24			
Responder, n(%)	8 (12.1%)	5 (12.8%)	13 (12.4%)
Unadjusted Inverse Relative Risk (95% CI)	1.06 (0.37, 3.01)		
p-value [1]	0.92		
Unadjusted Inverse Odds Ratio (95% CI)	1.07 (0.32, 3.52)		
p-value [1]	0.92		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.14, 0.12)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.04 (0.37, 2.95)		
p-value [2]	0.94		
Non-Responder, n(%)	58 (87.9%)	34 (87.2%)	92 (87.6%)
Non-missing	19 (28.8%)	18 (46.2%)	37 (35.2%)
Missing	39 (59.1%)	16 (41.0%)	55 (52.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

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Table 2.7407: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #7 at Week 24

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N = 66)	BAT (N = 39)	Total (N = 105)
MPN0107 - Dizziness at Week 24			
Responder, n(%)	4 (6.1%)	5 (12.8%)	9 (8.6%)
Unadjusted Inverse Relative Risk (95% CI)	2.12 (0.60, 7.41)		
p-value [1]	0.24		
Unadjusted Inverse Odds Ratio (95% CI)	2.28 (0.57, 9.06)		
p-value [1]	0.24		
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.19, 0.05)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Non-Responder, n(%)	62 (93.9%)	34 (87.2%)	96 (91.4%)
Non-missing	23 (34.8%)	18 (46.2%)	41 (39.0%)
Missing	39 (59.1%)	16 (41.0%)	55 (52.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

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Table 2.7408: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #8 at Week 24

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N = 66)	BAT (N = 39)	Total (N = 105)
MPN0108 - Numbness at Week 24			
Responder, n(%)	2 (3.0%)	4 (10.3%)	6 (5.7%)
Unadjusted Inverse Relative Risk (95% CI)	3.38 (0.65, 17.63)		
p-value [1]	0.15		
Unadjusted Inverse Odds Ratio (95% CI)	3.66 (0.64, 20.98)		
p-value [1]	0.15		
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.18, 0.03)		
Adjusted Inverse Relative Risk (95% CI) [2]	2.70 (0.61, 11.99)		
p-value [2]	0.19		
Non-Responder, n(%)	64 (97.0%)	35 (89.7%)	99 (94.3%)
Non-missing	25 (37.9%)	19 (48.7%)	44 (41.9%)
Missing	39 (59.1%)	16 (41.0%)	55 (52.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.7409: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #9 at Week 24

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N = 66)	BAT (N = 39)	Total (N = 105)
MPN0109 - Difficulty Sleeping at Week 24			
Responder, n(%)	9 (13.6%)	3 (7.7%)	12 (11.4%)
Unadjusted Inverse Relative Risk (95% CI)	0.56 (0.16, 1.96)		
p-value [1]	0.37		
Unadjusted Inverse Odds Ratio (95% CI)	0.53 (0.13, 2.08)		
p-value [1]	0.36		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.06, 0.18)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.50 (0.14, 1.75)		
p-value [2]	0.28		
Non-Responder, n(%)	57 (86.4%)	36 (92.3%)	93 (88.6%)
Non-missing	18 (27.3%)	20 (51.3%)	38 (36.2%)
Missing	39 (59.1%)	16 (41.0%)	55 (52.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.7410: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #10 at Week 24

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N = 66)	BAT (N = 39)	Total (N = 105)
MPN0110 - Depression at Week 24			
Responder, n(%)	5 (7.6%)	6 (15.4%)	11 (10.5%)
Unadjusted Inverse Relative Risk (95% CI)	2.03 (0.66, 6.22)		
p-value [1]	0.21		
Unadjusted Inverse Odds Ratio (95% CI)	2.22 (0.63, 7.82)		
p-value [1]	0.22		
Unadjusted Absolute Risk Difference (95% CI)	-0.08 (-0.21, 0.05)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.67 (0.58, 4.81)		
p-value [2]	0.35		
Non-Responder, n(%)	61 (92.4%)	33 (84.6%)	94 (89.5%)
Non-missing	22 (33.3%)	17 (43.6%)	39 (37.1%)
Missing	39 (59.1%)	16 (41.0%)	55 (52.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.7411: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #11 at Week 24

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N = 66)	BAT (N = 39)	Total (N = 105)
MPN0111 - Sexual at Week 24			
Responder, n(%)	5 (7.6%)	5 (12.8%)	10 (9.5%)
Unadjusted Inverse Relative Risk (95% CI)	1.69 (0.52, 5.48)		
p-value [1]	0.38		
Unadjusted Inverse Odds Ratio (95% CI)	1.79 (0.48, 6.64)		
p-value [1]	0.38		
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.18, 0.07)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.81 (0.60, 5.43)		
p-value [2]	0.29		
Non-Responder, n(%)	61 (92.4%)	34 (87.2%)	95 (90.5%)
Non-missing	22 (33.3%)	18 (46.2%)	40 (38.1%)
Missing	39 (59.1%)	16 (41.0%)	55 (52.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.7412: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #12 at Week 24

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N = 66)	BAT (N = 39)	Total (N = 105)
MPN0112 - Cough at Week 24			
Responder, n(%)	8 (12.1%)	4 (10.3%)	12 (11.4%)
Unadjusted Inverse Relative Risk (95% CI)	0.85 (0.27, 2.63)		
p-value [1]	0.77		
Unadjusted Inverse Odds Ratio (95% CI)	0.83 (0.23, 2.95)		
p-value [1]	0.77		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.10, 0.14)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Non-Responder, n(%)	58 (87.9%)	35 (89.7%)	93 (88.6%)
Non-missing	19 (28.8%)	19 (48.7%)	38 (36.2%)
Missing	39 (59.1%)	16 (41.0%)	55 (52.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

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Table 2.7413: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #13 at Week 24

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N = 66)	BAT (N = 39)	Total (N = 105)
MPN0113 - Night Sweats at Week 24			
Responder, n(%)	11 (16.7%)	5 (12.8%)	16 (15.2%)
Unadjusted Inverse Relative Risk (95% CI)	0.77 (0.29, 2.05)		
p-value [1]	0.60		
Unadjusted Inverse Odds Ratio (95% CI)	0.74 (0.24, 2.30)		
p-value [1]	0.60		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.10, 0.18)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.73 (0.28, 1.89)		
p-value [2]	0.52		
Non-Responder, n(%)	55 (83.3%)	34 (87.2%)	89 (84.8%)
Non-missing	16 (24.2%)	18 (46.2%)	34 (32.4%)
Missing	39 (59.1%)	16 (41.0%)	55 (52.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.7414: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #14 at Week 24
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N = 66)	BAT (N = 39)	Total (N = 105)
MPN0114 - Itching at Week 24			
Responder, n(%)	2 (3.0%)	2 (5.1%)	4 (3.8%)
Unadjusted Inverse Relative Risk (95% CI)	1.69 (0.25, 11.54)		
p-value [1]	0.59		
Unadjusted Inverse Odds Ratio (95% CI)	1.73 (0.23, 12.80)		
p-value [1]	0.59		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.10, 0.06)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Non-Responder, n(%)	64 (97.0%)	37 (94.9%)	101 (96.2%)
Non-missing	25 (37.9%)	21 (53.8%)	46 (43.8%)
Missing	39 (59.1%)	16 (41.0%)	55 (52.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

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Table 2.7415: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #15 at Week 24

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N = 66)	BAT (N = 39)	Total (N = 105)
MPN0115 - Bone Pain at Week 24			
Responder, n(%)	6 (9.1%)	5 (12.8%)	11 (10.5%)
Unadjusted Inverse Relative Risk (95% CI)	1.41 (0.46, 4.32)		
p-value [1]	0.55		
Unadjusted Inverse Odds Ratio (95% CI)	1.47 (0.42, 5.18)		
p-value [1]	0.55		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.16, 0.09)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.22 (0.44, 3.37)		
p-value [2]	0.71		
Non-Responder, n(%)	60 (90.9%)	34 (87.2%)	94 (89.5%)
Non-missing	21 (31.8%)	18 (46.2%)	39 (37.1%)
Missing	39 (59.1%)	16 (41.0%)	55 (52.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.7416: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #16 at Week 24

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N = 66)	BAT (N = 39)	Total (N = 105)
MPN0116 - Fever at Week 24			
Responder, n(%)	1 (1.5%)	2 (5.1%)	3 (2.9%)
Unadjusted Inverse Relative Risk (95% CI)	3.38 (0.32, 36.12)		
p-value [1]	0.31		
Unadjusted Inverse Odds Ratio (95% CI)	3.51 (0.31, 40.08)		
p-value [1]	0.31		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.11, 0.04)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Non-Responder, n(%)	65 (98.5%)	37 (94.9%)	102 (97.1%)
Non-missing	26 (39.4%)	21 (53.8%)	47 (44.8%)
Missing	39 (59.1%)	16 (41.0%)	55 (52.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

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Table 2.7417: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #17 at Week 24

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N = 66)	BAT (N = 39)	Total (N = 105)
MPN0117 - Weight Loss in 6 Months at Week 24			
Responder, n(%)	7 (10.6%)	1 (2.6%)	8 (7.6%)
Unadjusted Inverse Relative Risk (95% CI)	0.24 (0.03, 1.89)		
p-value [1]	0.18		
Unadjusted Inverse Odds Ratio (95% CI)	0.22 (0.03, 1.88)		
p-value [1]	0.17		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.01, 0.17)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.21 (0.03, 1.52)		
p-value [2]	0.12		
Non-Responder, n(%)	59 (89.4%)	38 (97.4%)	97 (92.4%)
Non-missing	20 (30.3%)	22 (56.4%)	42 (40.0%)
Missing	39 (59.1%)	16 (41.0%)	55 (52.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.7418: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #18 at Week 24

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N = 66)	BAT (N = 39)	Total (N = 105)
MPN0118 - Overall Quality of Life at Week 24			
Responder, n(%)	5 (7.6%)	6 (15.4%)	11 (10.5%)
Unadjusted Inverse Relative Risk (95% CI)	2.03 (0.66, 6.22)		
p-value [1]	0.21		
Unadjusted Inverse Odds Ratio (95% CI)	2.22 (0.63, 7.82)		
p-value [1]	0.22		
Unadjusted Absolute Risk Difference (95% CI)	-0.08 (-0.21, 0.05)		
Adjusted Inverse Relative Risk (95% CI) [2]	2.10 (0.63, 7.02)		
p-value [2]	0.23		
Non-Responder, n(%)	61 (92.4%)	33 (84.6%)	94 (89.5%)
Non-missing	22 (33.3%)	17 (43.6%)	39 (37.1%)
Missing	39 (59.1%)	16 (41.0%)	55 (52.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

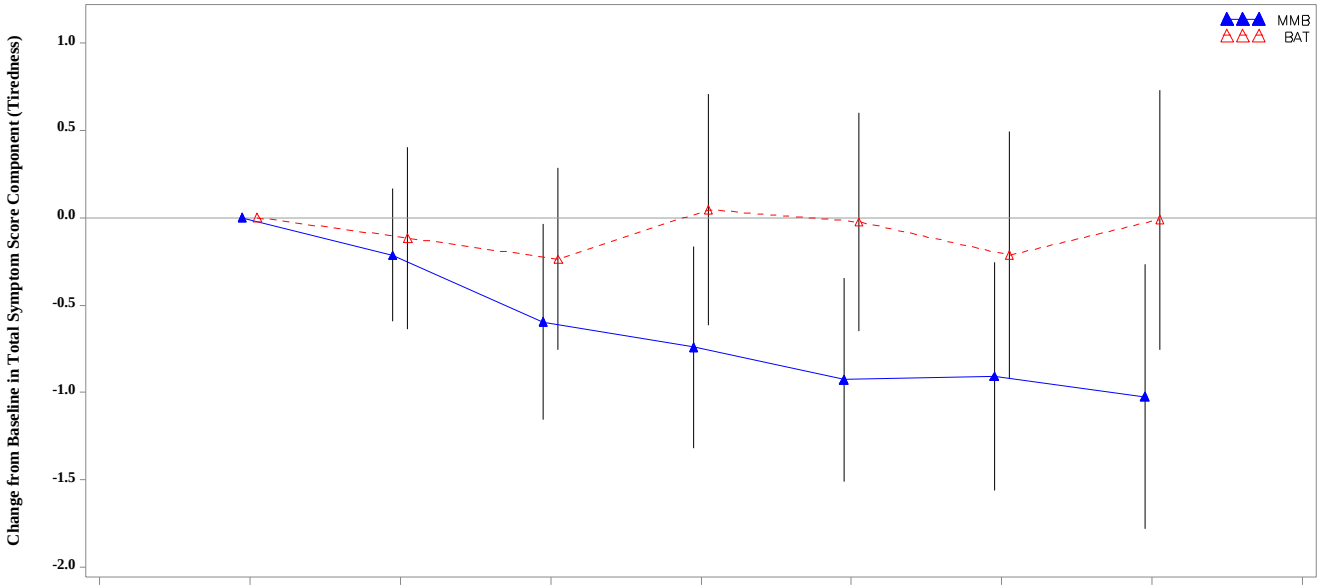
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

2.4.2 mMPN-SAF TSS

Figure 2.0801: Mean (incl. 95% CI) Plots of Change from Baseline (Including Baseline) for Individual TSS Scores (Every 4 Weeks) by Treatment
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=MMPN02-Wrst Inc Pst 24H: Tiredness



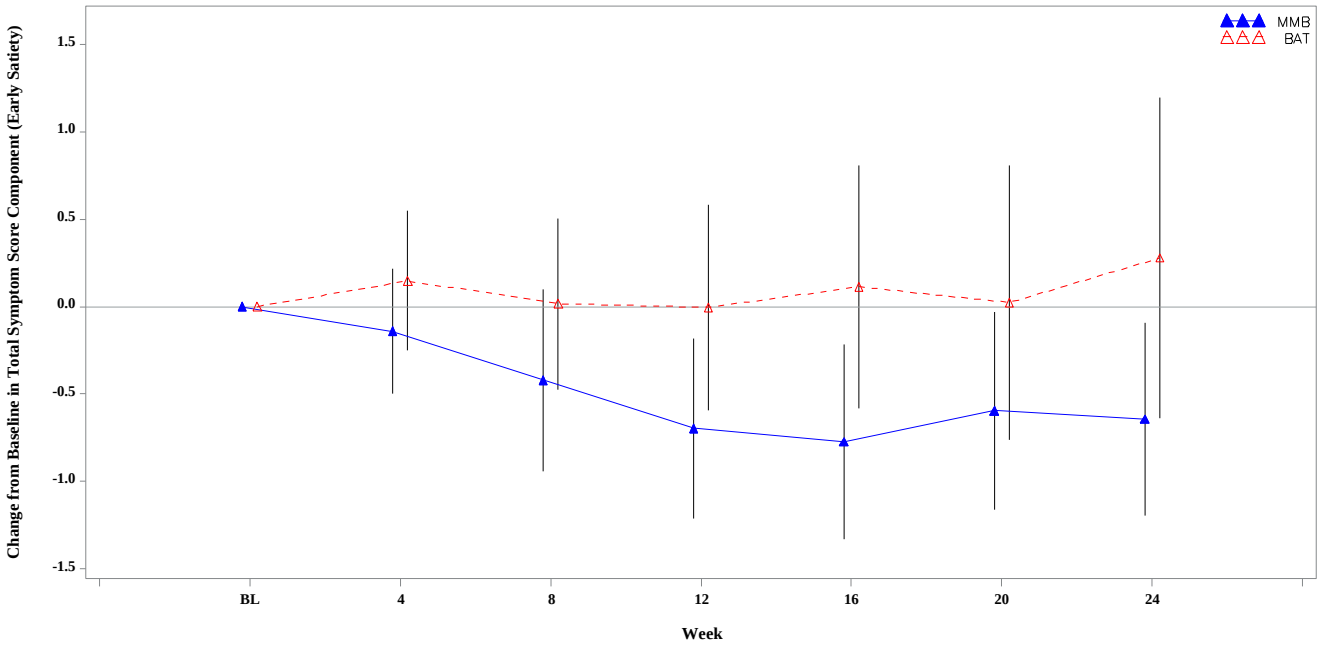
MMB	(n)	66	66	59	58	52	50	47
BAT	(n)	39	37	35	33	32	32	29

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
TSS = Total Symptom Score.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-line-ind-chg-tss.pdf 24AUG2023:16:50

Figure 2.0801: Mean (incl. 95% CI) Plots of Change from Baseline (Including Baseline) for Individual TSS Scores (Every 4 Weeks) by Treatment
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=MMPN02-Wrst Inc Pst 24H: Early Satiety



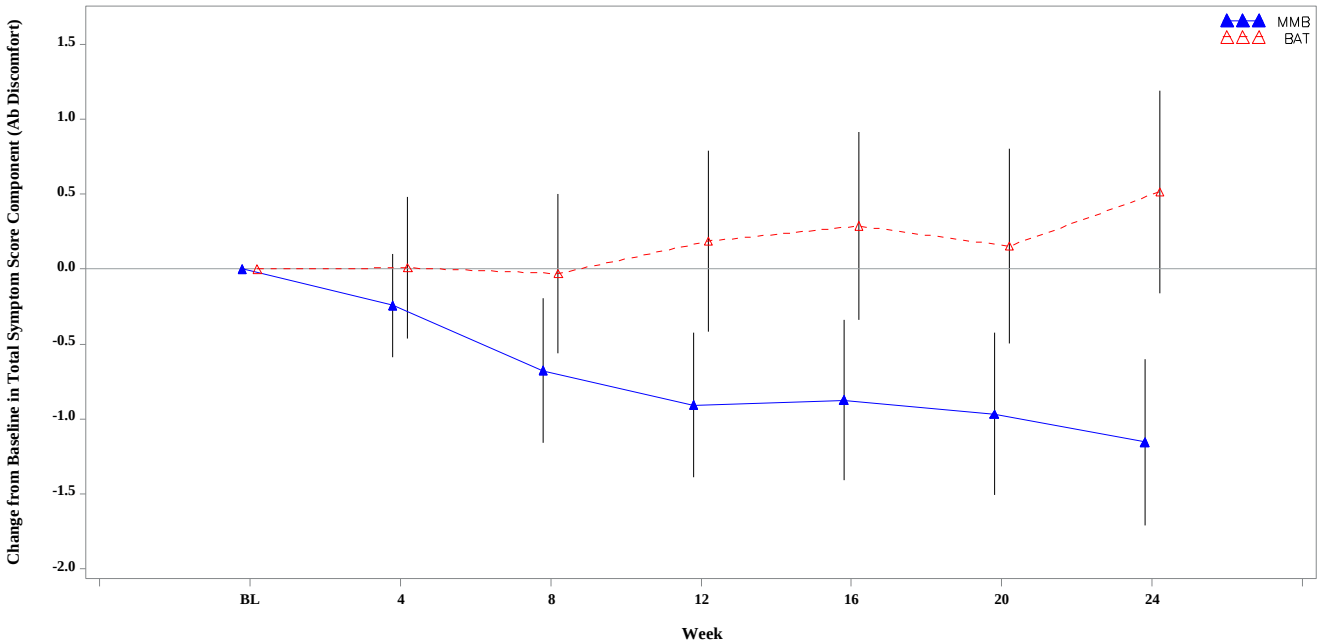
MMB	(n)	66	66	59	58	52	50	47
BAT	(n)	39	37	35	33	32	32	29

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
TSS = Total Symptom Score.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-line-ind-chg-tss.pdf 24AUG2023:16:50

Figure 2.0801: Mean (incl. 95% CI) Plots of Change from Baseline (Including Baseline) for Individual TSS Scores (Every 4 Weeks) by Treatment
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=MMPN02-Wrst Inc Pst 24H: Ab Discomfort



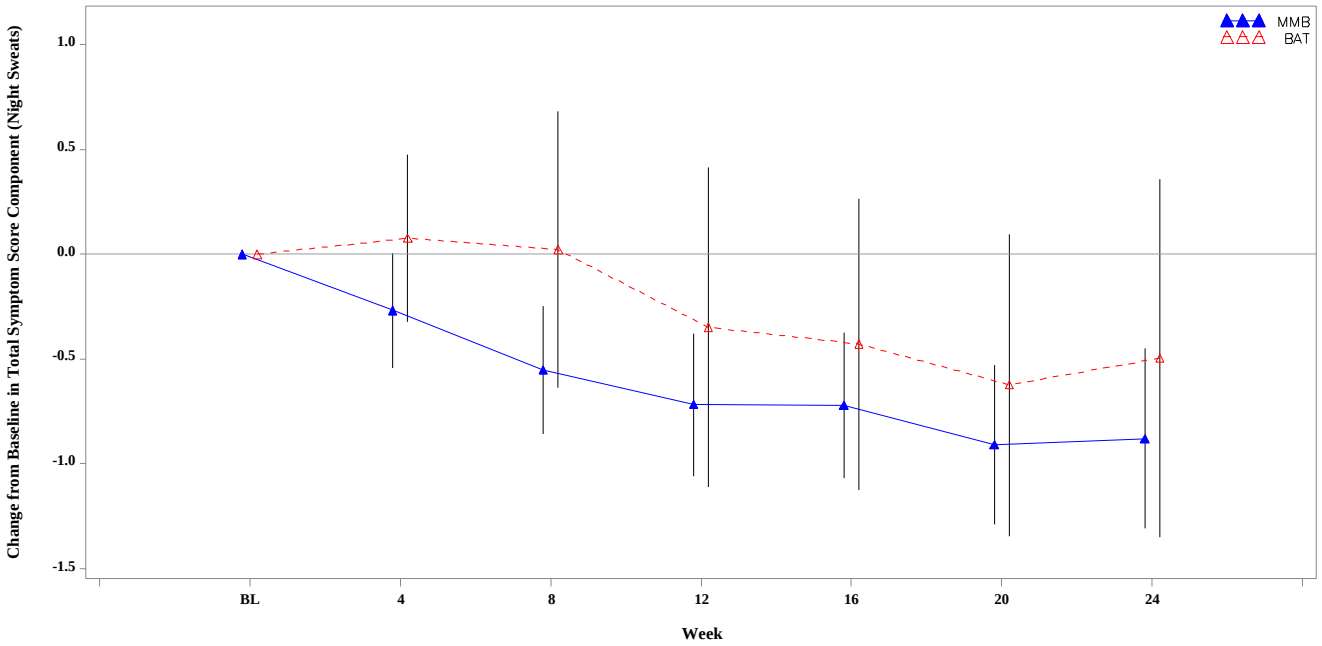
MMB	(n)	66	66	59	58	52	50	47
BAT	(n)	39	37	35	33	32	32	29

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
TSS = Total Symptom Score.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-line-ind-chg-tss.pdf 24AUG2023:16:50

Figure 2.0801: Mean (incl. 95% CI) Plots of Change from Baseline (Including Baseline) for Individual TSS Scores (Every 4 Weeks) by Treatment
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=MMPN02-Wrst Inc Pst 24H: Night Sweats



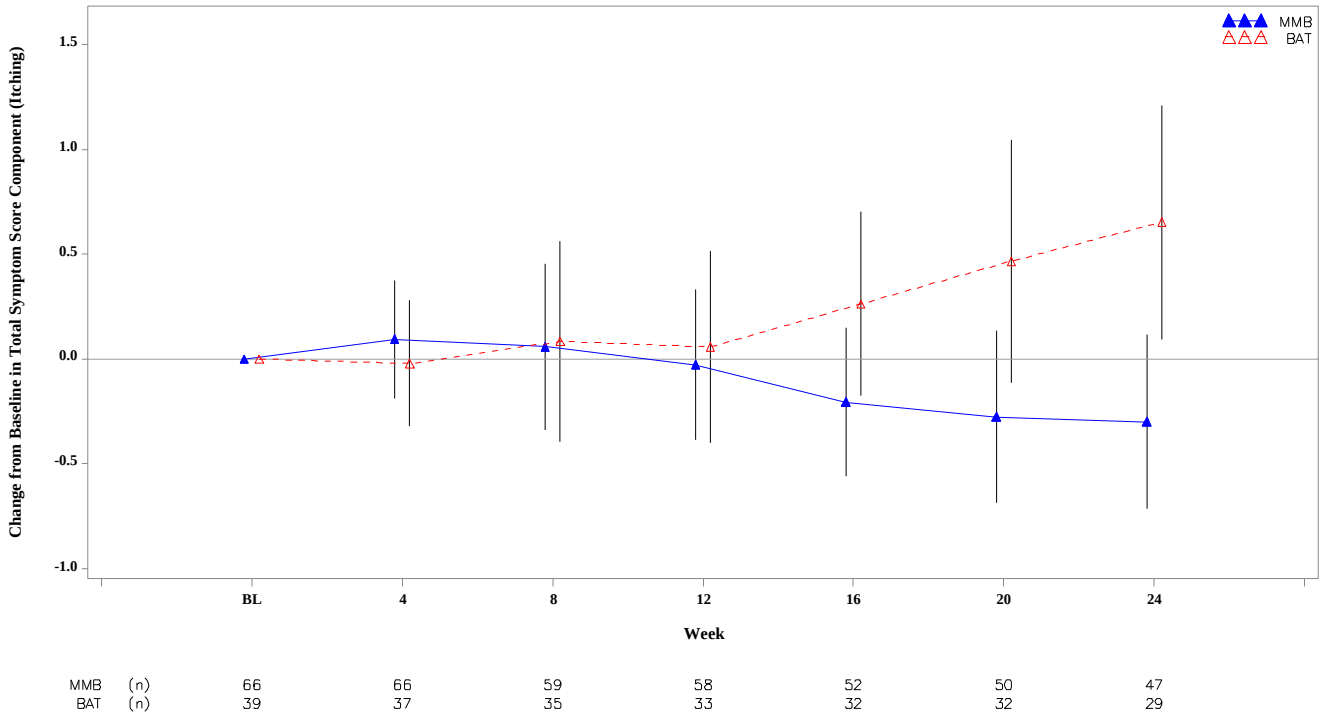
		BL	4	8	12	16	20	24
MMB	(n)	66	66	59	58	52	50	47
BAT	(n)	39	37	35	33	32	32	29

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
TSS = Total Symptom Score.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-line-ind-chg-tss.pdf 24AUG2023:16:50

Figure 2.0801: Mean (incl. 95% CI) Plots of Change from Baseline (Including Baseline) for Individual TSS Scores (Every 4 Weeks) by Treatment
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=MMPN02-Wrst Inc Pst 24H: Itching



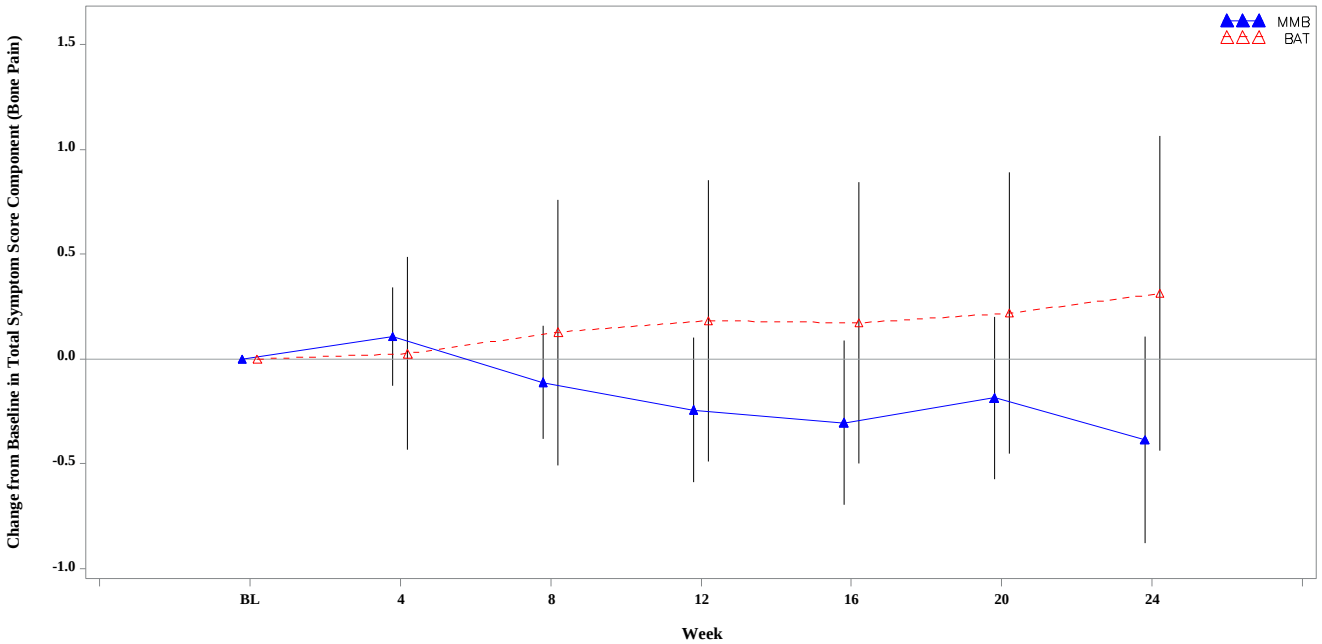
MMB	(n)	66	66	59	58	52	50	47
BAT	(n)	39	37	35	33	32	32	29

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
TSS = Total Symptom Score.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-line-ind-chg-tss.pdf 24AUG2023:16:50

Figure 2.0801: Mean (incl. 95% CI) Plots of Change from Baseline (Including Baseline) for Individual TSS Scores (Every 4 Weeks) by Treatment
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=MMPN02-Wrst Inc Pst 24H: Bone Pain



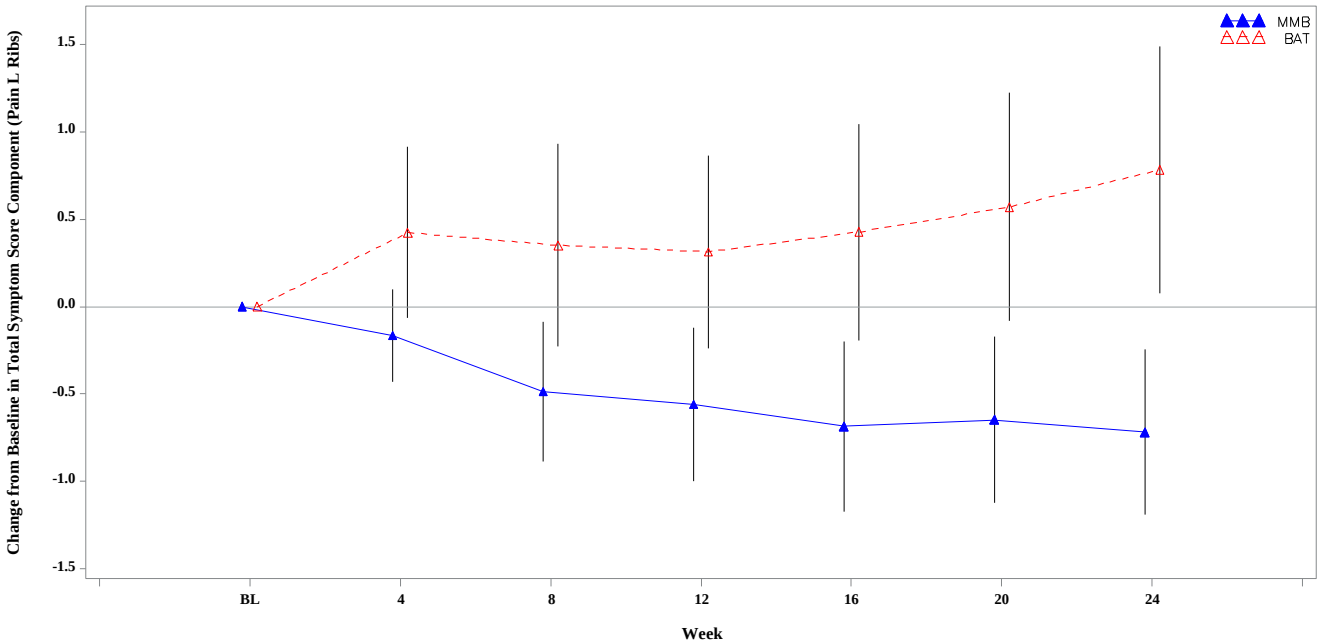
MMB	(n)	66	66	59	58	52	50	47
BAT	(n)	39	37	35	33	32	32	29

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
TSS = Total Symptom Score.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-line-ind-chg-tss.pdf 24AUG2023:16:50

Figure 2.0801: Mean (incl. 95% CI) Plots of Change from Baseline (Including Baseline) for Individual TSS Scores (Every 4 Weeks) by Treatment
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=MMPN02-Wrst Inc Pst 24H: Pain L Ribs



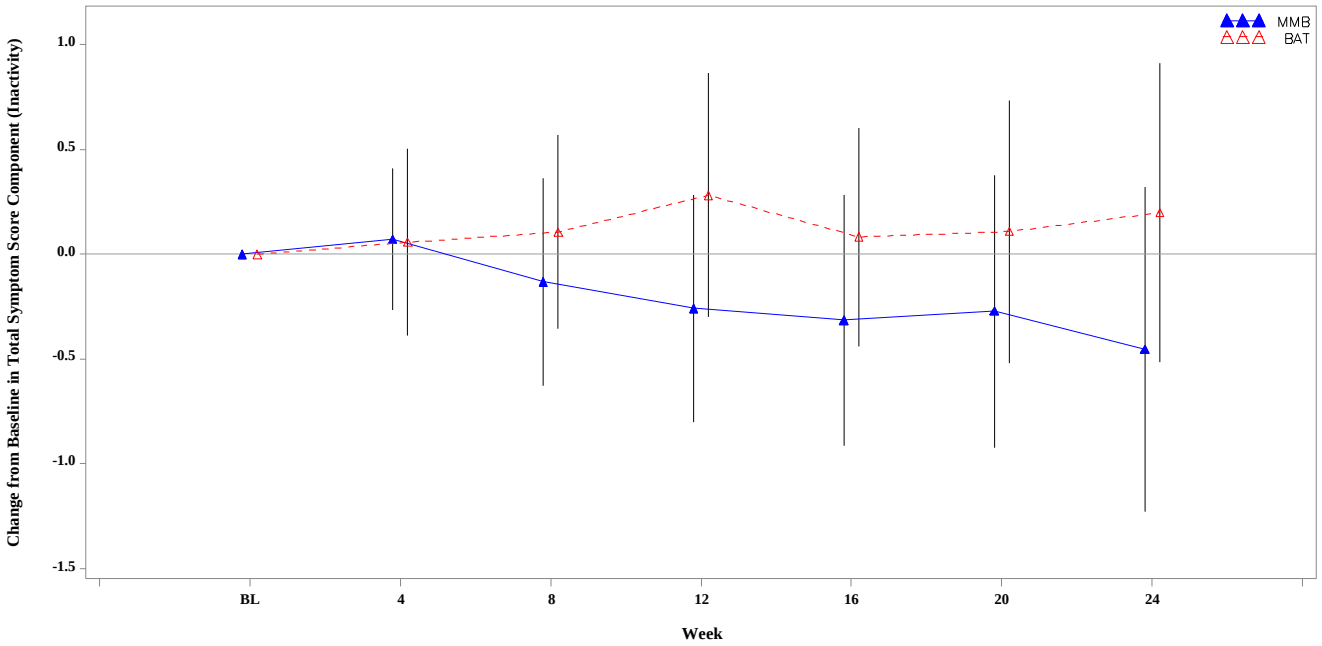
MMB	(n)	66	66	59	58	52	50	47
BAT	(n)	39	37	35	33	32	32	29

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
TSS = Total Symptom Score.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-line-ind-chg-tss.pdf 24AUG2023:16:50

Figure 2.0801: Mean (incl. 95% CI) Plots of Change from Baseline (Including Baseline) for Individual TSS Scores (Every 4 Weeks) by Treatment
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=MMPN02-Wrst Inc Pst 24H: Inactivity



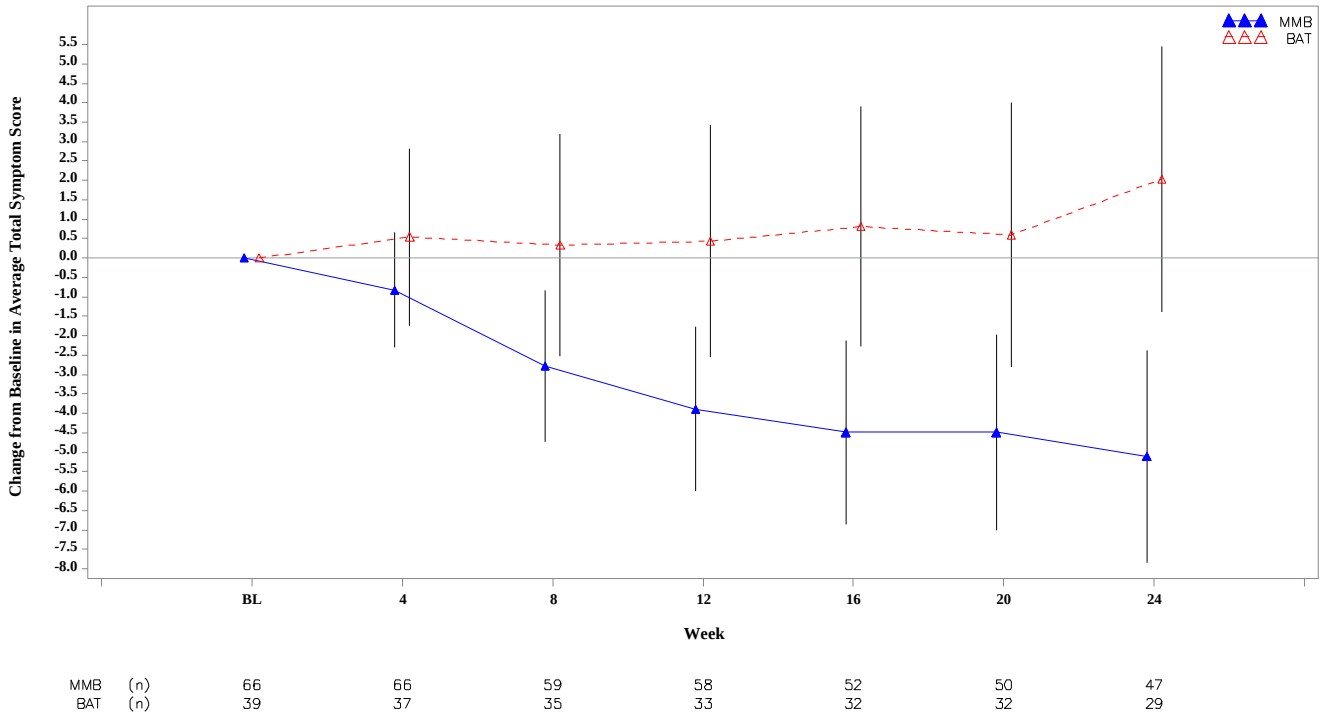
		BL	4	8	12	16	20	24
MMB	(n)	66	66	59	58	52	50	47
BAT	(n)	39	37	35	33	32	32	29

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
TSS = Total Symptom Score.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-line-ind-chg-tss.pdf 24AUG2023:16:50

Figure 2.0801: Mean (incl. 95% CI) Plots of Change from Baseline (Including Baseline) for Individual TSS Scores (Every 4 Weeks) by Treatment
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=Average Daily Total Symtom Score

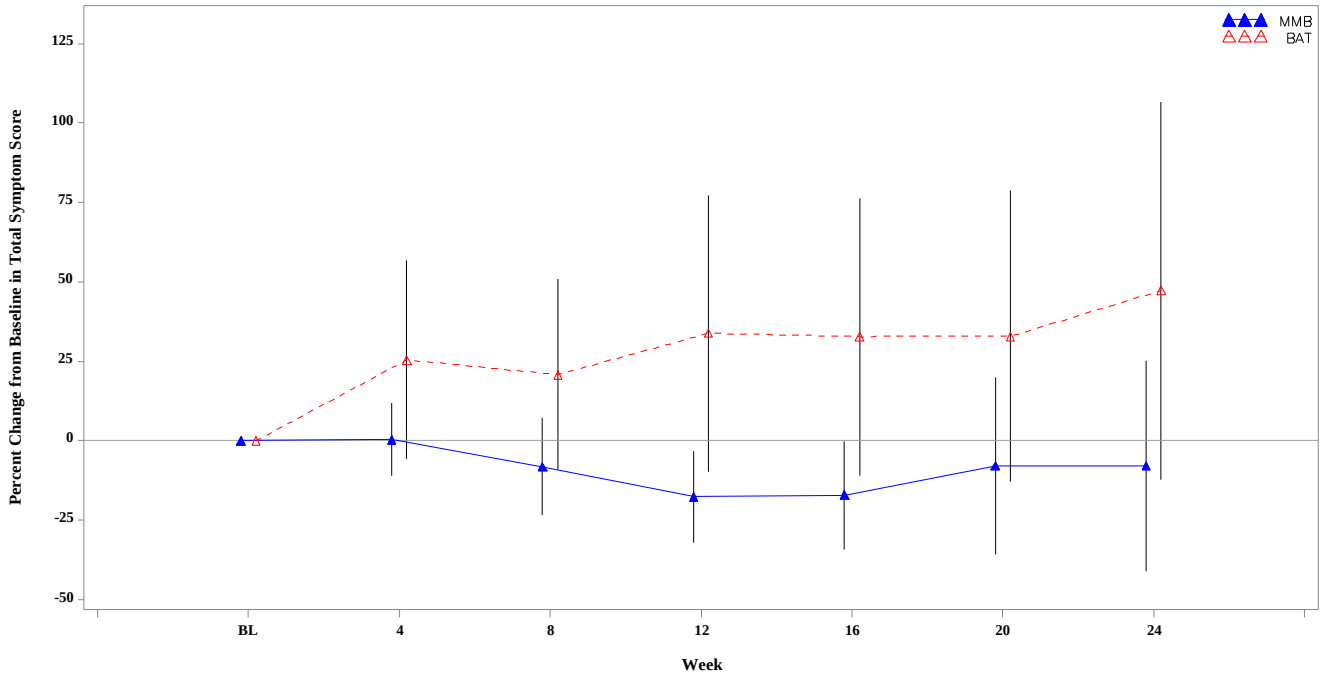


MMB	(n)	66	66	59	58	52	50	47
BAT	(n)	39	37	35	33	32	32	29

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
TSS = Total Symptom Score.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-line-ind-chg-tss.pdf 24AUG2023:16:50

Figure 2.0901: Mean (incl. 95% CI) Plots of % Change from Baseline (Including Baseline) in TSS Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set



MMB (n)	66	65	58	57	51	49	46
BAT (n)	39	34	32	30	29	29	27

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
TSS = Total Symptom Score.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-line-ind-pchg-tss.pdf 24AUG2023:16:50

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
TSS Item: Tiredness		
Tiredness at Baseline		
n	66	39
Mean (SD)	4.2 (2.50)	5.1 (3.13)
Median	3.9	6.1
Q1, Q3	2.1, 6.2	1.4, 8.0
Min, Max	0.0, 9.0	0.0, 9.7
Tiredness at Week 4		
n	66	37
Mean (SD)	4.0 (2.31)	4.9 (3.06)
Median	3.7	4.5
Q1, Q3	2.2, 5.6	2.4, 7.5
Min, Max	0.1, 9.7	0.0, 9.7
Change in Tiredness at Week 4 from Baseline		
n	66	37
Mean (SD)	-0.2 (1.55)	-0.1 (1.56)
Median	-0.2	0.0
Q1, Q3	-1.0, 0.8	-0.6, 0.8
Min, Max	-4.0, 4.0	-4.1, 2.8

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Change from Baseline at Week 4		
n [1]	66	37
n [2]	66	37
MMRM: Least Squares Mean [SE] (95% CI)	-0.17 [0.20] (-0.57, 0.23)	0.07 [0.24] (-0.42, 0.55)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.24 [0.30] (-0.84, 0.37)	
MMRM: P-value	0.44	
Corrected Hedges' g (95% CI)	-0.148 (-0.551, 0.255)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.55	
Percent Change in Tiredness at Week 4 from Baseline		
n	64	34
Mean (SD)	6.5 (57.44)	14.1 (72.32)
Median	-4.6	-1.0
Q1, Q3	-26.2, 25.0	-12.7, 16.3
Min, Max	-89.3, 253.3	-100.0, 242.8
Difference in Percent Change from Baseline at Week 4		
n [1]	64	34
n [2]	64	34
MMRM: Least Squares Mean [SE] (95% CI)	5.25 [8.14] (-10.91, 21.41)	22.22 [10.20] (1.97, 42.48)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-16.97 [12.64] (-42.08, 8.13)	
MMRM: P-value	0.18	
Corrected Hedges' g (95% CI)	-0.266 (-0.684, 0.151)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.63	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Tiredness at Week 8		
n	59	35
Mean (SD)	3.5 (2.06)	4.8 (3.06)
Median	3.3	5.3
Q1, Q3	2.0, 5.4	3.1, 7.1
Min, Max	0.1, 7.1	0.0, 10.0
Change in Tiredness at Week 8 from Baseline		
n	59	35
Mean (SD)	-0.6 (2.14)	-0.2 (1.52)
Median	-0.5	-0.1
Q1, Q3	-2.1, 0.8	-0.8, 0.3
Min, Max	-4.8, 5.5	-4.1, 2.7
Difference in Change from Baseline at Week 8		
n [1]	66	37
n [2]	59	35
MMRM: Least Squares Mean [SE] (95% CI)	-0.49 [0.24] (-0.96, -0.02)	0.06 [0.29] (-0.52, 0.64)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.55 [0.37] (-1.28, 0.17)	
MMRM: P-value	0.13	
Corrected Hedges' g (95% CI)	-0.306 (-0.726, 0.115)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.22	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Tiredness at Week 8 from Baseline		
n	57	32
Mean (SD)	-0.6 (75.81)	8.3 (84.56)
Median	-15.2	-6.4
Q1, Q3	-50.0, 10.7	-19.4, 8.5
Min, Max	-95.0, 350.2	-100.0, 382.2
Difference in Percent Change from Baseline at Week 8		
n [1]	64	34
n [2]	57	32
MMRM: Least Squares Mean [SE] (95% CI)	-0.44 [10.18] (-20.66, 19.78)	22.70 [13.14] (-3.40, 48.80)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-23.14 [16.31] (-55.53, 9.24)	
MMRM: P-value	0.16	
Corrected Hedges' g (95% CI)	-0.302 (-0.737, 0.133)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.26	
Tiredness at Week 12		
n	58	33
Mean (SD)	3.4 (2.15)	5.1 (3.03)
Median	3.1	5.1
Q1, Q3	2.0, 4.7	3.1, 7.8
Min, Max	0.0, 8.1	0.0, 10.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Tiredness at Week 12 from Baseline		
n	58	33
Mean (SD)	-0.7 (2.19)	0.0 (1.87)
Median	-0.7	0.0
Q1, Q3	-2.0, 0.7	-0.8, 1.2
Min, Max	-5.4, 4.5	-3.8, 6.1
Difference in Change from Baseline at Week 12		
n [1]	66	37
n [2]	58	33
MMRM: Least Squares Mean [SE] (95% CI)	-0.58 [0.25] (-1.08, -0.07)	0.42 [0.32] (-0.21, 1.05)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.99 [0.40] (-1.78, -0.21)	
MMRM: P-value	0.014	
Corrected Hedges' g (95% CI)	-0.519 (-0.953, -0.085)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.062	
Percent Change in Tiredness at Week 12 from Baseline		
n	56	30
Mean (SD)	-8.3 (67.56)	38.7 (173.20)
Median	-17.2	-2.8
Q1, Q3	-56.4, 12.1	-26.5, 15.1
Min, Max	-100.0, 195.3	-100.0, 854.1

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 12		
n [1]	64	34
n [2]	56	30
MMRM: Least Squares Mean [SE] (95% CI)	-5.99 [14.44] (-34.67, 22.69)	56.03 [19.28] (17.73, 94.33)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-62.02 [23.88] (-109.45, -14.59)	
MMRM: P-value	0.011	
Corrected Hedges' g (95% CI)	-0.573 (-1.025, -0.121)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.072	
Tiredness at Week 16		
n	52	32
Mean (SD)	3.2 (2.05)	5.1 (3.06)
Median	3.0	5.0
Q1, Q3	1.9, 4.2	2.6, 7.7
Min, Max	0.0, 7.2	0.0, 9.8
Change in Tiredness at Week 16 from Baseline		
n	52	32
Mean (SD)	-0.9 (2.10)	0.0 (1.74)
Median	-0.9	0.1
Q1, Q3	-2.2, 0.5	-1.0, 1.4
Min, Max	-5.9, 3.9	-4.6, 3.1

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Change from Baseline at Week 16		
n [1]	66	37
n [2]	52	32
MMRM: Least Squares Mean [SE] (95% CI)	-0.61 [0.26] (-1.12, -0.10)	0.34 [0.32] (-0.29, 0.97)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.95 [0.40] (-1.74, -0.16)	
MMRM: P-value	0.018	
Corrected Hedges' g (95% CI)	-0.516 (-0.963, -0.069)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.008	
Percent Change in Tiredness at Week 16 from Baseline		
n	50	29
Mean (SD)	-15.0 (55.93)	42.1 (148.76)
Median	-24.9	-1.3
Q1, Q3	-55.6, 20.0	-23.8, 22.6
Min, Max	-100.0, 161.9	-100.0, 600.0
Difference in Percent Change from Baseline at Week 16		
n [1]	64	34
n [2]	50	29
MMRM: Least Squares Mean [SE] (95% CI)	-10.57 [13.08] (-36.55, 15.42)	55.33 [16.93] (21.71, 88.94)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-65.89 [21.09] (-107.77, -24.01)	
MMRM: P-value	0.002	
Corrected Hedges' g (95% CI)	-0.709 (-1.180, -0.238)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.006	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Tiredness at Week 20		
n	50	32
Mean (SD)	3.2 (2.12)	4.9 (3.20)
Median	3.0	4.4
Q1, Q3	1.5, 4.2	3.1, 7.9
Min, Max	0.0, 7.3	0.0, 10.0
Change in Tiredness at Week 20 from Baseline		
n	50	32
Mean (SD)	-0.9 (2.30)	-0.2 (1.96)
Median	-0.8	-0.3
Q1, Q3	-2.5, 0.7	-1.1, 1.0
Min, Max	-6.2, 3.8	-4.9, 3.8
Difference in Change from Baseline at Week 20		
n [1]	66	37
n [2]	50	32
MMRM: Least Squares Mean [SE] (95% CI)	-0.61 [0.28] (-1.16, -0.05)	0.15 [0.35] (-0.54, 0.85)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.76 [0.44] (-1.63, 0.11)	
MMRM: P-value	0.085	
Corrected Hedges' g (95% CI)	-0.382 (-0.830, 0.065)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.031	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Tiredness at Week 20 from Baseline		
n	48	29
Mean (SD)	-12.6 (71.83)	45.9 (165.36)
Median	-31.0	-7.1
Q1, Q3	-62.7, 19.3	-31.5, 13.7
Min, Max	-100.0, 260.0	-100.0, 700.0
Difference in Percent Change from Baseline at Week 20		
n [1]	64	34
n [2]	48	29
MMRM: Least Squares Mean [SE] (95% CI)	-9.99 [15.00] (-39.78, 19.81)	58.97 [19.47] (20.30, 97.65)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-68.96 [24.33] (-117.28, -20.64)	
MMRM: P-value	0.006	
Corrected Hedges' g (95% CI)	-0.655 (-1.127, -0.182)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.016	
Tiredness at Week 24		
n	47	29
Mean (SD)	3.0 (2.14)	5.3 (3.21)
Median	2.8	5.6
Q1, Q3	1.5, 4.1	3.1, 8.1
Min, Max	0.0, 8.3	0.0, 10.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Tiredness at Week 24 from Baseline		
n	47	29
Mean (SD)	-1.0 (2.58)	0.0 (1.95)
Median	-0.8	0.1
Q1, Q3	-2.7, 0.7	-1.0, 1.6
Min, Max	-7.8, 4.4	-5.0, 3.8
Difference in Change from Baseline at Week 24		
n [1]	66	37
n [2]	47	29
MMRM: Least Squares Mean [SE] (95% CI)	-0.70 [0.30] (-1.29, -0.10)	0.25 [0.38] (-0.50, 1.00)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.95 [0.47] (-1.89, -0.01)	
MMRM: P-value	0.048	
Corrected Hedges' g (95% CI)	-0.458 (-0.927, 0.010)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.030	
Percent Change in Tiredness at Week 24 from Baseline		
n	45	27
Mean (SD)	-12.1 (71.64)	78.0 (294.40)
Median	-38.2	1.1
Q1, Q3	-63.5, 20.2	-21.4, 31.5
Min, Max	-100.0, 200.7	-100.0, 1475.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 24		
n [1]	64	34
n [2]	45	27
MMRM: Least Squares Mean [SE] (95% CI)	-10.78 [24.67] (-59.79, 38.23)	77.77 [32.35] (13.52, 142.03)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-88.56 [40.50] (-169.00, -8.11)	
MMRM: P-value	0.031	
Corrected Hedges' g (95% CI)	-0.526 (-1.011, -0.041)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.004	
TSS Item: Early Satiety		
Early Satiety at Baseline		
n	66	39
Mean (SD)	2.7 (2.32)	3.0 (3.07)
Median	2.3	2.4
Q1, Q3	0.8, 4.1	0.0, 5.7
Min, Max	0.0, 9.0	0.0, 9.9
Early Satiety at Week 4		
n	66	37
Mean (SD)	2.6 (2.20)	3.2 (3.13)
Median	2.1	2.4
Q1, Q3	1.0, 3.7	0.0, 6.0
Min, Max	0.0, 8.6	0.0, 9.7

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Early Satiety at Week 4 from Baseline		
n	66	37
Mean (SD)	-0.1 (1.45)	0.1 (1.20)
Median	-0.1	0.0
Q1, Q3	-0.9, 0.7	-0.1, 0.7
Min, Max	-4.1, 3.7	-3.2, 2.5
Difference in Change from Baseline at Week 4		
n [1]	66	37
n [2]	66	37
MMRM: Least Squares Mean [SE] (95% CI)	0.00 [0.18] (-0.36, 0.35)	0.24 [0.21] (-0.19, 0.66)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.24 [0.27] (-0.77, 0.29)	
MMRM: P-value	0.38	
Corrected Hedges' g (95% CI)	-0.168 (-0.571, 0.235)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.27	
Percent Change in Early Satiety at Week 4 from Baseline		
n	58	27
Mean (SD)	24.8 (195.25)	22.8 (85.81)
Median	-11.8	0.1
Q1, Q3	-49.3, 17.2	-11.4, 39.4
Min, Max	-100.0, 1326.9	-100.0, 340.7

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 4		
n [1]	58	27
n [2]	58	27
MMRM: Least Squares Mean [SE] (95% CI)	24.14 [23.77] (-23.18, 71.46)	31.36 [32.76] (-33.85, 96.56)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-7.21 [39.01] (-84.86, 70.44)	
MMRM: P-value	0.85	
Corrected Hedges' g (95% CI)	-0.040 (-0.497, 0.416)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.30	
Early Satiety at Week 8		
n	59	35
Mean (SD)	2.2 (2.20)	3.2 (3.16)
Median	1.6	2.5
Q1, Q3	0.3, 3.3	0.0, 5.3
Min, Max	0.0, 9.0	0.0, 10.0
Change in Early Satiety at Week 8 from Baseline		
n	59	35
Mean (SD)	-0.4 (2.00)	0.0 (1.43)
Median	-0.3	0.0
Q1, Q3	-1.6, 0.6	-0.3, 0.4
Min, Max	-5.0, 7.0	-4.2, 2.9

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Change from Baseline at Week 8		
n [1]	66	37
n [2]	59	35
MMRM: Least Squares Mean [SE] (95% CI)	-0.16 [0.23] (-0.62, 0.29)	0.17 [0.29] (-0.40, 0.75)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.34 [0.36] (-1.06, 0.38)	
MMRM: P-value	0.35	
Corrected Hedges' g (95% CI)	-0.191 (-0.610, 0.228)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.11	
Percent Change in Early Satiety at Week 8 from Baseline		
n	52	26
Mean (SD)	6.7 (128.36)	27.6 (125.32)
Median	-25.2	-0.1
Q1, Q3	-70.4, 21.5	-21.8, 41.3
Min, Max	-100.0, 543.8	-100.0, 556.3
Difference in Percent Change from Baseline at Week 8		
n [1]	58	27
n [2]	52	26
MMRM: Least Squares Mean [SE] (95% CI)	5.44 [19.48] (-33.33, 44.20)	38.02 [24.90] (-11.54, 87.57)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-32.58 [29.51] (-91.33, 26.17)	
MMRM: P-value	0.27	
Corrected Hedges' g (95% CI)	-0.237 (-0.709, 0.235)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.13	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Early Satiety at Week 12		
n	58	33
Mean (SD)	2.0 (2.11)	3.2 (3.16)
Median	1.5	2.5
Q1, Q3	0.2, 2.9	0.2, 4.8
Min, Max	0.0, 9.0	0.0, 10.0
Change in Early Satiety at Week 12 from Baseline		
n	58	33
Mean (SD)	-0.7 (1.95)	0.0 (1.65)
Median	-0.2	0.0
Q1, Q3	-2.0, 0.2	-0.3, 0.9
Min, Max	-5.6, 5.3	-4.1, 3.4
Difference in Change from Baseline at Week 12		
n [1]	66	37
n [2]	58	33
MMRM: Least Squares Mean [SE] (95% CI)	-0.38 [0.24] (-0.86, 0.09)	0.21 [0.30] (-0.39, 0.81)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.60 [0.38] (-1.35, 0.16)	
MMRM: P-value	0.12	
Corrected Hedges' g (95% CI)	-0.329 (-0.759, 0.101)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.022	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Early Satiety at Week 12 from Baseline		
n	51	24
Mean (SD)	-13.2 (97.36)	77.0 (293.75)
Median	-40.0	1.3
Q1, Q3	-82.1, 11.7	-36.6, 26.3
Min, Max	-100.0, 438.0	-100.0, 1192.3
Difference in Percent Change from Baseline at Week 12		
n [1]	58	27
n [2]	51	24
MMRM: Least Squares Mean [SE] (95% CI)	-12.39 [26.63] (-65.41, 40.62)	88.71 [36.30] (16.45, 160.97)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-101.10 [43.52] (-187.73, -14.47)	
MMRM: P-value	0.023	
Corrected Hedges' g (95% CI)	-0.537 (-1.030, -0.044)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.045	
Early Satiety at Week 16		
n	52	32
Mean (SD)	1.9 (2.28)	3.4 (3.23)
Median	1.1	2.9
Q1, Q3	0.0, 2.9	0.1, 5.8
Min, Max	0.0, 9.0	0.0, 9.5

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Early Satiety at Week 16 from Baseline		
n	52	32
Mean (SD)	-0.8 (2.00)	0.1 (1.92)
Median	-0.5	0.0
Q1, Q3	-2.1, 0.1	-0.9, 1.3
Min, Max	-6.6, 3.4	-4.7, 4.3
Difference in Change from Baseline at Week 16		
n [1]	66	37
n [2]	52	32
MMRM: Least Squares Mean [SE] (95% CI)	-0.41 [0.26] (-0.93, 0.10)	0.36 [0.32] (-0.29, 1.00)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.77 [0.41] (-1.58, 0.03)	
MMRM: P-value	0.060	
Corrected Hedges' g (95% CI)	-0.414 (-0.859, 0.030)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.014	
Percent Change in Early Satiety at Week 16 from Baseline		
n	44	24
Mean (SD)	-17.9 (108.24)	76.1 (328.97)
Median	-47.8	0.1
Q1, Q3	-96.4, 0.0	-36.5, 40.0
Min, Max	-100.0, 468.8	-100.0, 1487.5

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 16		
n [1]	58	27
n [2]	44	24
MMRM: Least Squares Mean [SE] (95% CI)	-8.16 [29.90] (-67.68, 51.36)	87.31 [41.06] (5.59, 169.03)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-95.47 [49.41] (-193.82, 2.88)	
MMRM: P-value	0.057	
Corrected Hedges' g (95% CI)	-0.473 (-0.977, 0.030)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.006	
Early Satiety at Week 20		
n	50	32
Mean (SD)	2.0 (2.29)	3.3 (3.27)
Median	1.3	3.2
Q1, Q3	0.0, 3.1	0.0, 6.4
Min, Max	0.0, 9.0	0.0, 9.0
Change in Early Satiety at Week 20 from Baseline		
n	50	32
Mean (SD)	-0.6 (2.00)	0.0 (2.17)
Median	-0.1	0.0
Q1, Q3	-1.7, 0.7	-0.9, 1.2
Min, Max	-6.9, 3.1	-4.4, 4.3

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Change from Baseline at Week 20		
n [1]	66	37
n [2]	50	32
MMRM: Least Squares Mean [SE] (95% CI)	-0.32 [0.27] (-0.86, 0.22)	0.26 [0.34] (-0.42, 0.95)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.59 [0.43] (-1.44, 0.27)	
MMRM: P-value	0.18	
Corrected Hedges' g (95% CI)	-0.301 (-0.747, 0.145)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.11	
Percent Change in Early Satiety at Week 20 from Baseline		
n	42	24
Mean (SD)	-1.0 (138.17)	50.3 (267.91)
Median	-37.1	-12.2
Q1, Q3	-91.7, 16.4	-55.6, 27.3
Min, Max	-100.0, 550.0	-100.0, 1138.5
Difference in Percent Change from Baseline at Week 20		
n [1]	58	27
n [2]	42	24
MMRM: Least Squares Mean [SE] (95% CI)	6.56 [27.97] (-49.12, 62.24)	61.43 [37.40] (-13.01, 135.88)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-54.87 [45.21] (-144.85, 35.11)	
MMRM: P-value	0.23	
Corrected Hedges' g (95% CI)	-0.298 (-0.802, 0.206)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.063	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Early Satiety at Week 24		
n	47	29
Mean (SD)	1.9 (2.22)	3.6 (3.37)
Median	1.5	3.3
Q1, Q3	0.0, 3.2	0.2, 7.0
Min, Max	0.0, 9.0	0.0, 10.0
Change in Early Satiety at Week 24 from Baseline		
n	47	29
Mean (SD)	-0.6 (1.88)	0.3 (2.41)
Median	-0.1	0.0
Q1, Q3	-1.4, 0.6	-0.6, 1.3
Min, Max	-7.1, 1.9	-4.4, 5.0
Difference in Change from Baseline at Week 24		
n [1]	66	37
n [2]	47	29
MMRM: Least Squares Mean [SE] (95% CI)	-0.36 [0.28] (-0.91, 0.20)	0.34 [0.35] (-0.36, 1.03)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.69 [0.44] (-1.57, 0.18)	
MMRM: P-value	0.12	
Corrected Hedges' g (95% CI)	-0.360 (-0.827, 0.106)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.048	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in Early Satiety at Week 24 from Baseline			
n	40	22	
Mean (SD)	-2.7 (122.41)	58.8 (264.61)	
Median	-31.1	-3.5	
Q1, Q3	-96.5, 25.7	-57.4, 38.8	
Min, Max	-100.0, 431.5	-100.0, 1131.5	
Difference in Percent Change from Baseline at Week 24			
n [1]	58	27	
n [2]	40	22	
MMRM: Least Squares Mean [SE] (95% CI)	1.93 [26.35] (-50.53, 54.38)	59.51 [34.84] (-9.84, 128.86)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-57.59 [42.07] (-141.32, 26.15)		
MMRM: P-value	0.17		
Corrected Hedges' g (95% CI)	-0.343 (-0.867, 0.180)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.017		
TSS Item: Abdominal Discomfort			
Abdominal Discomfort at Baseline			
n	66	39	
Mean (SD)	2.6 (2.28)	3.2 (2.90)	
Median	2.0	2.8	
Q1, Q3	0.4, 4.3	0.4, 4.9	
Min, Max	0.0, 8.7	0.0, 9.6	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Abdominal Discomfort at Week 4			
n	66	37	
Mean (SD)	2.4 (2.15)	3.3 (3.04)	
Median	2.1	2.9	
Q1, Q3	0.3, 3.9	0.4, 5.1	
Min, Max	0.0, 7.4	0.0, 10.0	
Change in Abdominal Discomfort at Week 4 from Baseline			
n	66	37	
Mean (SD)	-0.2 (1.40)	0.0 (1.42)	
Median	-0.1	0.0	
Q1, Q3	-1.0, 0.3	-0.7, 0.5	
Min, Max	-4.6, 3.2	-2.9, 3.7	
Difference in Change from Baseline at Week 4			
n [1]	66	37	
n [2]	66	37	
MMRM: Least Squares Mean [SE] (95% CI)	-0.20 [0.19] (-0.57, 0.16)	0.12 [0.22] (-0.32, 0.57)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.33 [0.28] (-0.88, 0.22)		
MMRM: P-value	0.24		
Corrected Hedges' g (95% CI)	-0.225 (-0.629, 0.179)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.43		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Abdominal Discomfort at Week 4 from Baseline		
n	56	29
Mean (SD)	22.0 (140.82)	84.6 (490.32)
Median	-16.4	-1.6
Q1, Q3	-41.7, 24.9	-29.4, 25.0
Min, Max	-100.0, 781.0	-100.0, 2622.2
Difference in Percent Change from Baseline at Week 4		
n [1]	56	29
n [2]	56	29
MMRM: Least Squares Mean [SE] (95% CI)	23.01 [41.79] (-60.18, 106.19)	93.25 [56.51] (-19.22, 205.73)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-70.24 [69.72] (-209.03, 68.54)	
MMRM: P-value	0.32	
Corrected Hedges' g (95% CI)	-0.225 (-0.674, 0.225)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.69	
Abdominal Discomfort at Week 8		
n	59	35
Mean (SD)	1.8 (1.91)	3.3 (3.12)
Median	1.6	2.3
Q1, Q3	0.2, 2.9	0.8, 6.3
Min, Max	0.0, 7.2	0.0, 10.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Abdominal Discomfort at Week 8 from Baseline		
n	59	35
Mean (SD)	-0.7 (1.86)	0.0 (1.54)
Median	-0.1	0.0
Q1, Q3	-1.4, 0.1	-0.8, 0.7
Min, Max	-5.3, 5.6	-3.1, 3.6
Difference in Change from Baseline at Week 8		
n [1]	66	37
n [2]	59	35
MMRM: Least Squares Mean [SE] (95% CI)	-0.47 [0.22] (-0.92, -0.03)	0.11 [0.28] (-0.44, 0.66)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.58 [0.35] (-1.27, 0.10)	
MMRM: P-value	0.095	
Corrected Hedges' g (95% CI)	-0.342 (-0.763, 0.079)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.063	
Percent Change in Abdominal Discomfort at Week 8 from Baseline		
n	49	28
Mean (SD)	11.3 (158.65)	26.7 (185.06)
Median	-30.9	-4.1
Q1, Q3	-73.1, 6.8	-48.5, 21.0
Min, Max	-100.0, 561.1	-100.0, 920.8

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 8		
n [1]	56	29
n [2]	49	28
MMRM: Least Squares Mean [SE] (95% CI)	13.28 [24.14] (-34.78, 61.33)	35.32 [29.78] (-23.96, 94.59)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-22.04 [37.14] (-95.97, 51.88)	
MMRM: P-value	0.55	
Corrected Hedges' g (95% CI)	-0.132 (-0.597, 0.333)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.10	
Abdominal Discomfort at Week 12		
n	58	33
Mean (SD)	1.7 (1.79)	3.5 (3.23)
Median	1.2	2.9
Q1, Q3	0.1, 2.9	1.0, 5.9
Min, Max	0.0, 7.5	0.0, 10.0
Change in Abdominal Discomfort at Week 12 from Baseline		
n	58	33
Mean (SD)	-0.9 (1.84)	0.2 (1.71)
Median	-0.5	0.0
Q1, Q3	-1.6, 0.0	-0.5, 1.0
Min, Max	-5.8, 3.0	-3.6, 4.4

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Change from Baseline at Week 12		
n [1]	66	37
n [2]	58	33
MMRM: Least Squares Mean [SE] (95% CI)	-0.65 [0.25] (-1.14, -0.16)	0.36 [0.31] (-0.25, 0.97)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.01 [0.38] (-1.77, -0.24)	
MMRM: P-value	0.010	
Corrected Hedges' g (95% CI)	-0.544 (-0.979, -0.110)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.009	
Percent Change in Abdominal Discomfort at Week 12 from Baseline		
n	48	26
Mean (SD)	15.6 (191.20)	51.3 (240.31)
Median	-38.3	-0.8
Q1, Q3	-80.4, 10.3	-51.0, 23.5
Min, Max	-100.0, 966.7	-100.0, 1030.8
Difference in Percent Change from Baseline at Week 12		
n [1]	56	29
n [2]	48	26
MMRM: Least Squares Mean [SE] (95% CI)	21.75 [30.37] (-38.70, 82.20)	61.99 [39.24] (-16.12, 140.09)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-40.24 [48.67] (-137.11, 56.64)	
MMRM: P-value	0.41	
Corrected Hedges' g (95% CI)	-0.192 (-0.671, 0.286)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.054	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Abdominal Discomfort at Week 16			
n	52	32	
Mean (SD)	1.8 (1.85)	3.6 (3.30)	
Median	1.3	3.0	
Q1, Q3	0.1, 3.0	0.5, 5.4	
Min, Max	0.0, 7.5	0.0, 10.0	
Change in Abdominal Discomfort at Week 16 from Baseline			
n	52	32	
Mean (SD)	-0.9 (1.91)	0.3 (1.74)	
Median	-0.3	0.0	
Q1, Q3	-1.8, 0.3	-0.7, 1.2	
Min, Max	-6.2, 1.7	-3.9, 4.3	
Difference in Change from Baseline at Week 16			
n [1]	66	37	
n [2]	52	32	
MMRM: Least Squares Mean [SE] (95% CI)	-0.56 [0.25] (-1.06, -0.05)	0.49 [0.32] (-0.15, 1.12)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.05 [0.40] (-1.84, -0.25)		
MMRM: P-value	0.010		
Corrected Hedges' g (95% CI)	-0.568 (-1.017, -0.119)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.017		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Abdominal Discomfort at Week 16 from Baseline		
n	42	25
Mean (SD)	-5.3 (121.07)	65.6 (273.83)
Median	-42.3	1.5
Q1, Q3	-81.3, 23.5	-39.3, 28.6
Min, Max	-100.0, 478.8	-100.0, 1008.3
Difference in Percent Change from Baseline at Week 16		
n [1]	56	29
n [2]	42	25
MMRM: Least Squares Mean [SE] (95% CI)	29.26 [31.55] (-33.54, 92.06)	73.71 [41.07] (-8.04, 155.46)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-44.45 [50.91] (-145.77, 56.88)	
MMRM: P-value	0.39	
Corrected Hedges' g (95% CI)	-0.215 (-0.711, 0.282)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.029	
Abdominal Discomfort at Week 20		
n	50	32
Mean (SD)	1.5 (1.81)	3.4 (3.20)
Median	0.9	2.9
Q1, Q3	0.0, 2.9	0.4, 5.7
Min, Max	0.0, 7.4	0.0, 9.9

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Abdominal Discomfort at Week 20 from Baseline		
n	50	32
Mean (SD)	-1.0 (1.91)	0.2 (1.81)
Median	-0.5	0.0
Q1, Q3	-1.6, 0.2	-0.9, 1.2
Min, Max	-6.8, 1.8	-4.0, 4.0
Difference in Change from Baseline at Week 20		
n [1]	66	37
n [2]	50	32
MMRM: Least Squares Mean [SE] (95% CI)	-0.71 [0.26] (-1.23, -0.19)	0.35 [0.33] (-0.30, 1.01)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.07 [0.41] (-1.89, -0.25)	
MMRM: P-value	0.011	
Corrected Hedges' g (95% CI)	-0.568 (-1.020, -0.116)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.010	
Percent Change in Abdominal Discomfort at Week 20 from Baseline		
n	40	25
Mean (SD)	-14.4 (128.05)	47.7 (213.91)
Median	-48.7	3.0
Q1, Q3	-92.9, 7.7	-55.8, 28.7
Min, Max	-100.0, 587.5	-100.0, 860.3

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 20		
n [1]	56	29
n [2]	40	25
MMRM: Least Squares Mean [SE] (95% CI)	17.92 [27.58] (-36.99, 72.82)	57.49 [34.93] (-12.04, 127.02)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-39.57 [43.44] (-126.04, 46.90)	
MMRM: P-value	0.37	
Corrected Hedges' g (95% CI)	-0.224 (-0.725, 0.277)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.069	
Abdominal Discomfort at Week 24		
n	47	29
Mean (SD)	1.4 (1.65)	3.8 (3.32)
Median	0.5	3.3
Q1, Q3	0.0, 2.4	1.1, 6.6
Min, Max	0.0, 6.8	0.0, 10.0
Change in Abdominal Discomfort at Week 24 from Baseline		
n	47	29
Mean (SD)	-1.2 (1.89)	0.5 (1.78)
Median	-0.7	0.4
Q1, Q3	-2.0, 0.0	-0.6, 1.5
Min, Max	-7.0, 1.6	-3.3, 4.8

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Change from Baseline at Week 24		
n [1]	66	37
n [2]	47	29
MMRM: Least Squares Mean [SE] (95% CI)	-0.81 [0.27] (-1.34, -0.29)	0.53 [0.34] (-0.13, 1.20)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.35 [0.42] (-2.18, -0.51)	
MMRM: P-value	0.002	
Corrected Hedges' g (95% CI)	-0.734 (-1.211, -0.256)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	< 0.001	
Percent Change in Abdominal Discomfort at Week 24 from Baseline		
n	37	23
Mean (SD)	-31.0 (101.96)	66.2 (223.71)
Median	-61.9	11.1
Q1, Q3	-83.8, -12.0	-26.9, 28.7
Min, Max	-100.0, 487.5	-100.0, 833.3
Difference in Percent Change from Baseline at Week 24		
n [1]	56	29
n [2]	37	23
MMRM: Least Squares Mean [SE] (95% CI)	20.29 [28.37] (-36.18, 76.77)	64.36 [36.05] (-7.39, 136.11)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-44.07 [44.89] (-133.41, 45.28)	
MMRM: P-value	0.33	
Corrected Hedges' g (95% CI)	-0.252 (-0.774, 0.271)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.003	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
TSS Item: Night Sweats		
Night Sweats at Baseline		
n	66	39
Mean (SD)	2.0 (2.01)	2.8 (3.30)
Median	1.7	1.3
Q1, Q3	0.0, 3.0	0.0, 6.3
Min, Max	0.0, 7.9	0.0, 10.0
Night Sweats at Week 4		
n	66	37
Mean (SD)	1.7 (1.98)	2.9 (3.15)
Median	1.2	1.8
Q1, Q3	0.1, 2.5	0.0, 6.1
Min, Max	0.0, 8.5	0.0, 9.5
Change in Night Sweats at Week 4 from Baseline		
n	66	37
Mean (SD)	-0.3 (1.12)	0.1 (1.19)
Median	0.0	0.0
Q1, Q3	-0.7, 0.1	-0.2, 0.5
Min, Max	-3.0, 2.9	-4.4, 2.8

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Change from Baseline at Week 4		
n [1]	66	37
n [2]	66	37
MMRM: Least Squares Mean [SE] (95% CI)	-0.29 [0.15] (-0.59, 0.01)	0.18 [0.19] (-0.19, 0.55)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.47 [0.23] (-0.93, -0.02)	
MMRM: P-value	0.043	
Corrected Hedges' g (95% CI)	-0.394 (-0.800, 0.012)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.041	
Percent Change in Night Sweats at Week 4 from Baseline		
n	46	22
Mean (SD)	8.1 (103.87)	12.3 (67.67)
Median	-16.0	0.6
Q1, Q3	-42.3, 8.5	-14.2, 14.1
Min, Max	-97.6, 476.9	-100.0, 207.8
Difference in Percent Change from Baseline at Week 4		
n [1]	46	22
n [2]	46	22
MMRM: Least Squares Mean [SE] (95% CI)	0.31 [14.21] (-28.09, 28.72)	20.68 [20.08] (-19.46, 60.82)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-20.37 [24.74] (-69.82, 29.08)	
MMRM: P-value	0.41	
Corrected Hedges' g (95% CI)	-0.210 (-0.720, 0.299)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.20	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Night Sweats at Week 8			
n	59	35	
Mean (SD)	1.4 (1.70)	2.8 (3.17)	
Median	1.0	1.3	
Q1, Q3	0.0, 2.3	0.0, 6.0	
Min, Max	0.0, 8.2	0.0, 9.6	
Change in Night Sweats at Week 8 from Baseline			
n	59	35	
Mean (SD)	-0.6 (1.16)	0.0 (1.92)	
Median	0.0	0.0	
Q1, Q3	-1.0, 0.1	-0.6, 0.7	
Min, Max	-3.6, 2.3	-5.9, 3.5	
Difference in Change from Baseline at Week 8			
n [1]	66	37	
n [2]	59	35	
MMRM: Least Squares Mean [SE] (95% CI)	-0.41 [0.19] (-0.79, -0.04)	0.10 [0.24] (-0.37, 0.57)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.51 [0.30] (-1.11, 0.08)		
MMRM: P-value	0.089		
Corrected Hedges' g (95% CI)	-0.354 (-0.775, 0.068)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.028		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Night Sweats at Week 8 from Baseline		
n	40	21
Mean (SD)	-5.9 (135.89)	10.7 (101.04)
Median	-24.9	-2.6
Q1, Q3	-59.5, 0.5	-57.1, 25.9
Min, Max	-100.0, 757.1	-100.0, 318.8
Difference in Percent Change from Baseline at Week 8		
n [1]	46	22
n [2]	40	21
MMRM: Least Squares Mean [SE] (95% CI)	2.30 [19.42] (-36.51, 41.11)	18.15 [27.68] (-37.18, 73.49)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-15.85 [33.99] (-83.79, 52.08)	
MMRM: P-value	0.64	
Corrected Hedges' g (95% CI)	-0.126 (-0.655, 0.403)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.17	
Night Sweats at Week 12		
n	58	33
Mean (SD)	1.3 (1.54)	2.5 (3.06)
Median	0.7	1.0
Q1, Q3	0.0, 1.9	0.0, 4.0
Min, Max	0.0, 6.6	0.0, 9.4

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Night Sweats at Week 12 from Baseline		
n	58	33
Mean (SD)	-0.7 (1.29)	-0.3 (2.15)
Median	-0.5	0.0
Q1, Q3	-1.4, 0.0	-1.0, 0.2
Min, Max	-4.2, 3.6	-6.6, 3.8
Difference in Change from Baseline at Week 12		
n [1]	66	37
n [2]	58	33
MMRM: Least Squares Mean [SE] (95% CI)	-0.63 [0.20] (-1.03, -0.22)	-0.14 [0.26] (-0.65, 0.37)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.49 [0.32] (-1.13, 0.15)	
MMRM: P-value	0.13	
Corrected Hedges' g (95% CI)	-0.317 (-0.747, 0.112)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.069	
Percent Change in Night Sweats at Week 12 from Baseline		
n	40	20
Mean (SD)	-32.4 (63.27)	-1.4 (114.93)
Median	-40.6	-16.5
Q1, Q3	-68.6, -19.3	-76.7, 6.2
Min, Max	-100.0, 239.3	-100.0, 418.8

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 12			
n [1]	46	22	
n [2]	40	20	
MMRM: Least Squares Mean [SE] (95% CI)	-32.31 [13.64] (-59.57, -5.04)	8.78 [18.92] (-29.05, 46.60)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-41.08 [23.38] (-87.82, 5.66)		
MMRM: P-value	0.084		
Corrected Hedges' g (95% CI)	-0.473 (-1.016, 0.070)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.15		
Night Sweats at Week 16			
n	52	32	
Mean (SD)	1.2 (1.75)	2.5 (3.09)	
Median	0.4	1.0	
Q1, Q3	0.0, 1.6	0.0, 3.7	
Min, Max	0.0, 8.2	0.0, 10.0	
Change in Night Sweats at Week 16 from Baseline			
n	52	32	
Mean (SD)	-0.7 (1.24)	-0.4 (1.93)	
Median	-0.2	0.0	
Q1, Q3	-1.2, 0.0	-1.2, 0.0	
Min, Max	-4.4, 2.0	-5.4, 3.5	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Change from Baseline at Week 16		
n [1]	66	37
n [2]	52	32
MMRM: Least Squares Mean [SE] (95% CI)	-0.62 [0.19] (-1.00, -0.23)	-0.14 [0.24] (-0.63, 0.34)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.47 [0.30] (-1.08, 0.13)	
MMRM: P-value	0.12	
Corrected Hedges' g (95% CI)	-0.338 (-0.782, 0.105)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.18	
Percent Change in Night Sweats at Week 16 from Baseline		
n	34	20
Mean (SD)	-46.2 (36.76)	1.1 (126.94)
Median	-43.7	-19.5
Q1, Q3	-84.4, -14.6	-60.4, 10.1
Min, Max	-100.0, 17.1	-100.0, 487.5
Difference in Percent Change from Baseline at Week 16		
n [1]	46	22
n [2]	34	20
MMRM: Least Squares Mean [SE] (95% CI)	-43.78 [13.84] (-71.46, -16.11)	9.79 [18.79] (-27.77, 47.36)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-53.57 [23.28] (-100.10, -7.04)	
MMRM: P-value	0.025	
Corrected Hedges' g (95% CI)	-0.644 (-1.210, -0.079)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.12	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Night Sweats at Week 20		
n	50	32
Mean (SD)	1.0 (1.66)	2.3 (2.97)
Median	0.1	1.0
Q1, Q3	0.0, 1.2	0.0, 3.8
Min, Max	0.0, 6.8	0.0, 10.0
Change in Night Sweats at Week 20 from Baseline		
n	50	32
Mean (SD)	-0.9 (1.34)	-0.6 (2.00)
Median	-0.3	0.0
Q1, Q3	-1.6, 0.0	-1.7, 0.1
Min, Max	-5.1, 1.3	-4.7, 4.1
Difference in Change from Baseline at Week 20		
n [1]	66	37
n [2]	50	32
MMRM: Least Squares Mean [SE] (95% CI)	-0.80 [0.20] (-1.21, -0.40)	-0.34 [0.25] (-0.85, 0.17)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.46 [0.32] (-1.10, 0.17)	
MMRM: P-value	0.15	
Corrected Hedges' g (95% CI)	-0.318 (-0.765, 0.128)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.18	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Night Sweats at Week 20 from Baseline		
n	32	20
Mean (SD)	-48.4 (59.24)	-12.8 (107.36)
Median	-59.0	-27.1
Q1, Q3	-96.0, -18.5	-76.1, 10.2
Min, Max	-100.0, 180.0	-100.0, 393.8
Difference in Percent Change from Baseline at Week 20		
n [1]	46	22
n [2]	32	20
MMRM: Least Squares Mean [SE] (95% CI)	-45.84 [13.39] (-72.60, -19.07)	-3.63 [18.14] (-39.89, 32.63)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-42.21 [22.53] (-87.25, 2.83)	
MMRM: P-value	0.066	
Corrected Hedges' g (95% CI)	-0.534 (-1.102, 0.034)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.21	
Night Sweats at Week 24		
n	47	29
Mean (SD)	1.0 (1.59)	2.5 (3.11)
Median	0.1	1.0
Q1, Q3	0.0, 1.4	0.0, 3.9
Min, Max	0.0, 6.6	0.0, 10.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Night Sweats at Week 24 from Baseline		
n	47	29
Mean (SD)	-0.9 (1.46)	-0.5 (2.24)
Median	-0.2	0.0
Q1, Q3	-1.8, 0.0	-1.1, 0.3
Min, Max	-5.6, 1.3	-6.3, 4.5
Difference in Change from Baseline at Week 24		
n [1]	66	37
n [2]	47	29
MMRM: Least Squares Mean [SE] (95% CI)	-0.72 [0.23] (-1.18, -0.26)	-0.32 [0.29] (-0.90, 0.25)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.39 [0.37] (-1.12, 0.33)	
MMRM: P-value	0.28	
Corrected Hedges' g (95% CI)	-0.247 (-0.711, 0.218)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.16	
Percent Change in Night Sweats at Week 24 from Baseline		
n	30	18
Mean (SD)	-43.8 (52.51)	-9.3 (110.33)
Median	-47.0	-24.2
Q1, Q3	-95.8, -12.5	-66.7, 0.5
Min, Max	-100.0, 107.1	-100.0, 393.8

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 24		
n [1]	46	22
n [2]	30	18
MMRM: Least Squares Mean [SE] (95% CI)	-41.94 [13.50] (-68.94, -14.95)	-7.25 [17.85] (-42.93, 28.43)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-34.69 [22.32] (-79.30, 9.92)	
MMRM: P-value	0.13	
Corrected Hedges' g (95% CI)	-0.457 (-1.049, 0.134)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.23	
TSS Item: Itching		
Itching at Baseline		
n	66	39
Mean (SD)	1.2 (1.61)	1.4 (2.12)
Median	0.1	0.6
Q1, Q3	0.0, 2.4	0.0, 1.3
Min, Max	0.0, 6.0	0.0, 8.7
Itching at Week 4		
n	66	37
Mean (SD)	1.3 (1.85)	1.4 (2.18)
Median	0.4	0.8
Q1, Q3	0.0, 1.7	0.0, 1.4
Min, Max	0.0, 8.1	0.0, 8.9

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Itching at Week 4 from Baseline		
n	66	37
Mean (SD)	0.1 (1.15)	0.0 (0.90)
Median	0.0	0.0
Q1, Q3	-0.3, 0.2	0.0, 0.3
Min, Max	-1.8, 6.6	-3.1, 2.6
Difference in Change from Baseline at Week 4		
n [1]	66	37
n [2]	66	37
MMRM: Least Squares Mean [SE] (95% CI)	0.13 [0.15] (-0.16, 0.41)	0.01 [0.18] (-0.34, 0.37)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.11 [0.22] (-0.33, 0.55)	
MMRM: P-value	0.61	
Corrected Hedges' g (95% CI)	0.098 (-0.305, 0.501)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.72	
Percent Change in Itching at Week 4 from Baseline		
n	35	23
Mean (SD)	33.8 (137.02)	28.0 (112.74)
Median	-12.6	3.4
Q1, Q3	-40.8, 34.7	-45.8, 44.8
Min, Max	-84.9, 479.3	-100.0, 322.4

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 4		
n [1]	35	23
n [2]	35	23
MMRM: Least Squares Mean [SE] (95% CI)	45.38 [24.50] (-3.78, 94.54)	34.53 [26.23] (-18.10, 87.17)
MMRM: Least Squares Mean Difference [SE] (95% CI)	10.84 [34.71] (-58.80, 80.49)	
MMRM: P-value	0.76	
Corrected Hedges' g (95% CI)	0.078 (-0.449, 0.604)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.73	
Itching at Week 8		
n	59	35
Mean (SD)	1.1 (1.70)	1.6 (2.48)
Median	0.2	0.8
Q1, Q3	0.0, 2.0	0.0, 1.7
Min, Max	0.0, 8.4	0.0, 8.1
Change in Itching at Week 8 from Baseline		
n	59	35
Mean (SD)	0.1 (1.52)	0.1 (1.40)
Median	0.0	0.0
Q1, Q3	-0.7, 0.3	-0.2, 0.8
Min, Max	-3.1, 6.8	-4.6, 4.3

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Change from Baseline at Week 8		
n [1]	66	37
n [2]	59	35
MMRM: Least Squares Mean [SE] (95% CI)	0.20 [0.19] (-0.18, 0.59)	0.12 [0.25] (-0.37, 0.61)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.09 [0.31] (-0.53, 0.70)	
MMRM: P-value	0.78	
Corrected Hedges' g (95% CI)	0.057 (-0.361, 0.475)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.45	
Percent Change in Itching at Week 8 from Baseline		
n	31	23
Mean (SD)	14.7 (140.14)	45.0 (140.97)
Median	-27.4	3.0
Q1, Q3	-82.1, 28.7	-65.0, 119.0
Min, Max	-100.0, 432.7	-100.0, 437.5
Difference in Percent Change from Baseline at Week 8		
n [1]	35	23
n [2]	31	23
MMRM: Least Squares Mean [SE] (95% CI)	27.02 [26.41] (-25.98, 80.02)	51.61 [27.80] (-4.17, 107.40)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-24.59 [37.20] (-99.23, 50.05)	
MMRM: P-value	0.51	
Corrected Hedges' g (95% CI)	-0.171 (-0.712, 0.369)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.50	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Itching at Week 12		
n	58	33
Mean (SD)	1.2 (1.51)	1.5 (2.45)
Median	0.4	0.8
Q1, Q3	0.0, 2.0	0.0, 1.8
Min, Max	0.0, 5.7	0.0, 9.5
Change in Itching at Week 12 from Baseline		
n	58	33
Mean (SD)	0.0 (1.37)	0.1 (1.29)
Median	0.0	0.0
Q1, Q3	-0.5, 0.4	0.0, 0.7
Min, Max	-3.9, 3.9	-5.0, 2.6
Difference in Change from Baseline at Week 12		
n [1]	66	37
n [2]	58	33
MMRM: Least Squares Mean [SE] (95% CI)	0.07 [0.18] (-0.29, 0.43)	0.19 [0.23] (-0.26, 0.64)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.12 [0.28] (-0.69, 0.44)	
MMRM: P-value	0.67	
Corrected Hedges' g (95% CI)	-0.090 (-0.517, 0.338)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.31	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Itching at Week 12 from Baseline		
n	32	22
Mean (SD)	25.7 (147.71)	48.2 (157.89)
Median	-25.3	9.9
Q1, Q3	-65.5, 39.8	-27.9, 75.0
Min, Max	-100.0, 425.0	-100.0, 475.0
Difference in Percent Change from Baseline at Week 12		
n [1]	35	23
n [2]	32	22
MMRM: Least Squares Mean [SE] (95% CI)	37.77 [27.82] (-18.06, 93.60)	57.53 [29.99] (-2.64, 117.70)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-19.76 [39.82] (-99.67, 60.15)	
MMRM: P-value	0.62	
Corrected Hedges' g (95% CI)	-0.129 (-0.672, 0.414)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.72	
Itching at Week 16		
n	52	32
Mean (SD)	0.9 (1.31)	1.8 (2.51)
Median	0.2	1.0
Q1, Q3	0.0, 1.6	0.0, 2.3
Min, Max	0.0, 5.2	0.0, 8.8

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Itching at Week 16 from Baseline		
n	52	32
Mean (SD)	-0.2 (1.28)	0.3 (1.22)
Median	0.0	0.1
Q1, Q3	-0.4, 0.0	0.0, 1.0
Min, Max	-4.0, 3.7	-3.7, 2.7
Difference in Change from Baseline at Week 16		
n [1]	66	37
n [2]	52	32
MMRM: Least Squares Mean [SE] (95% CI)	-0.01 [0.18] (-0.37, 0.35)	0.47 [0.23] (0.01, 0.92)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.48 [0.29] (-1.04, 0.09)	
MMRM: P-value	0.099	
Corrected Hedges' g (95% CI)	-0.361 (-0.805, 0.082)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.015	
Percent Change in Itching at Week 16 from Baseline		
n	27	21
Mean (SD)	6.0 (140.44)	64.9 (174.42)
Median	-34.1	25.0
Q1, Q3	-66.7, 15.5	-28.6, 111.1
Min, Max	-100.0, 575.0	-100.0, 687.5

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 16		
n [1]	35	23
n [2]	27	21
MMRM: Least Squares Mean [SE] (95% CI)	28.77 [31.01] (-33.46, 91.00)	91.50 [33.67] (23.94, 159.06)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-62.73 [44.75] (-152.53, 27.07)	
MMRM: P-value	0.17	
Corrected Hedges' g (95% CI)	-0.390 (-0.966, 0.186)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.061	
Itching at Week 20		
n	50	32
Mean (SD)	0.8 (1.27)	2.0 (2.66)
Median	0.1	1.0
Q1, Q3	0.0, 1.7	0.0, 2.5
Min, Max	0.0, 5.2	0.0, 8.7
Change in Itching at Week 20 from Baseline		
n	50	32
Mean (SD)	-0.3 (1.44)	0.5 (1.60)
Median	0.0	0.0
Q1, Q3	-0.9, 0.0	0.0, 1.0
Min, Max	-4.2, 3.9	-3.7, 4.8

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Change from Baseline at Week 20		
n [1]	66	37
n [2]	50	32
MMRM: Least Squares Mean [SE] (95% CI)	-0.10 [0.21] (-0.53, 0.32)	0.67 [0.27] (0.14, 1.20)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.78 [0.34] (-1.44, -0.11)	
MMRM: P-value	0.023	
Corrected Hedges' g (95% CI)	-0.509 (-0.960, -0.059)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.013	
Percent Change in Itching at Week 20 from Baseline		
n	26	21
Mean (SD)	39.2 (284.19)	104.9 (218.48)
Median	-63.0	49.8
Q1, Q3	-88.6, 8.3	-7.3, 157.1
Min, Max	-100.0, 1175.0	-100.0, 750.0
Difference in Percent Change from Baseline at Week 20		
n [1]	35	23
n [2]	26	21
MMRM: Least Squares Mean [SE] (95% CI)	56.58 [46.22] (-36.15, 149.32)	138.05 [52.78] (32.14, 243.96)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-81.47 [69.62] (-221.16, 58.23)	
MMRM: P-value	0.25	
Corrected Hedges' g (95% CI)	-0.336 (-0.915, 0.243)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.060	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Itching at Week 24		
n	47	29
Mean (SD)	0.7 (0.93)	2.1 (2.86)
Median	0.1	1.0
Q1, Q3	0.0, 1.4	0.0, 2.4
Min, Max	0.0, 3.3	0.0, 8.9
Change in Itching at Week 24 from Baseline		
n	47	29
Mean (SD)	-0.3 (1.42)	0.7 (1.47)
Median	0.0	0.2
Q1, Q3	-0.8, 0.1	0.0, 1.0
Min, Max	-4.5, 3.3	-2.0, 5.8
Difference in Change from Baseline at Week 24		
n [1]	66	37
n [2]	47	29
MMRM: Least Squares Mean [SE] (95% CI)	-0.13 [0.21] (-0.55, 0.29)	0.66 [0.27] (0.13, 1.18)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.79 [0.33] (-1.45, -0.12)	
MMRM: P-value	0.020	
Corrected Hedges' g (95% CI)	-0.539 (-1.010, -0.069)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.003	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Itching at Week 24 from Baseline		
n	23	19
Mean (SD)	34.3 (245.65)	109.5 (218.98)
Median	-60.4	39.7
Q1, Q3	-95.7, 0.0	-6.5, 171.4
Min, Max	-100.0, 950.0	-100.0, 725.0
Difference in Percent Change from Baseline at Week 24		
n [1]	35	23
n [2]	23	19
MMRM: Least Squares Mean [SE] (95% CI)	48.47 [41.53] (-34.86, 131.81)	119.36 [46.70] (25.65, 213.07)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-70.88 [61.84] (-194.98, 53.21)	
MMRM: P-value	0.26	
Corrected Hedges' g (95% CI)	-0.346 (-0.958, 0.266)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.026	
TSS Item: Bone Pain		
Bone Pain at Baseline		
n	66	39
Mean (SD)	2.2 (2.26)	2.8 (2.58)
Median	1.9	1.9
Q1, Q3	0.0, 3.3	0.0, 5.3
Min, Max	0.0, 8.4	0.0, 8.1

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Bone Pain at Week 4		
n	66	37
Mean (SD)	2.3 (2.36)	2.9 (2.88)
Median	1.7	1.8
Q1, Q3	0.0, 3.8	0.0, 5.0
Min, Max	0.0, 7.3	0.0, 8.7
Change in Bone Pain at Week 4 from Baseline		
n	66	37
Mean (SD)	0.1 (0.95)	0.0 (1.38)
Median	0.0	0.0
Q1, Q3	-0.3, 0.4	-0.3, 0.8
Min, Max	-2.1, 3.8	-4.2, 2.8
Difference in Change from Baseline at Week 4		
n [1]	66	37
n [2]	66	37
MMRM: Least Squares Mean [SE] (95% CI)	0.12 [0.16] (-0.20, 0.44)	0.04 [0.19] (-0.34, 0.42)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.08 [0.24] (-0.39, 0.55)	
MMRM: P-value	0.74	
Corrected Hedges' g (95% CI)	0.062 (-0.340, 0.465)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.79	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Bone Pain at Week 4 from Baseline		
n	47	27
Mean (SD)	14.2 (93.70)	4.3 (46.90)
Median	-8.0	1.9
Q1, Q3	-19.8, 19.2	-26.0, 41.1
Min, Max	-100.0, 527.6	-95.3, 113.5
Difference in Percent Change from Baseline at Week 4		
n [1]	47	27
n [2]	47	27
MMRM: Least Squares Mean [SE] (95% CI)	16.19 [13.16] (-10.08, 42.45)	5.82 [16.14] (-26.39, 38.04)
MMRM: Least Squares Mean Difference [SE] (95% CI)	10.36 [20.13] (-29.81, 50.54)	
MMRM: P-value	0.61	
Corrected Hedges' g (95% CI)	0.117 (-0.357, 0.590)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.81	
Bone Pain at Week 8		
n	59	35
Mean (SD)	2.0 (2.20)	3.0 (3.19)
Median	1.2	1.8
Q1, Q3	0.0, 3.5	0.0, 6.3
Min, Max	0.0, 6.8	0.0, 9.9

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Bone Pain at Week 8 from Baseline		
n	59	35
Mean (SD)	-0.1 (1.03)	0.1 (1.84)
Median	0.0	0.0
Q1, Q3	-0.5, 0.3	-0.4, 1.1
Min, Max	-3.6, 2.6	-4.4, 4.6
Difference in Change from Baseline at Week 8		
n [1]	66	37
n [2]	59	35
MMRM: Least Squares Mean [SE] (95% CI)	0.00 [0.20] (-0.39, 0.39)	0.23 [0.24] (-0.26, 0.71)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.22 [0.30] (-0.82, 0.38)	
MMRM: P-value	0.47	
Corrected Hedges' g (95% CI)	-0.148 (-0.567, 0.271)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.52	
Percent Change in Bone Pain at Week 8 from Baseline		
n	41	25
Mean (SD)	9.6 (118.31)	13.4 (76.58)
Median	-8.0	3.7
Q1, Q3	-45.9, 30.3	-40.0, 50.0
Min, Max	-100.0, 600.0	-100.0, 215.4

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 8		
n [1]	47	27
n [2]	41	25
MMRM: Least Squares Mean [SE] (95% CI)	13.75 [16.91] (-19.99, 47.50)	17.22 [21.07] (-24.83, 59.27)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-3.47 [26.48] (-56.31, 49.37)	
MMRM: P-value	0.90	
Corrected Hedges' g (95% CI)	-0.032 (-0.529, 0.465)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.68	
Bone Pain at Week 12		
n	58	33
Mean (SD)	1.8 (2.11)	2.9 (3.35)
Median	0.9	1.1
Q1, Q3	0.0, 3.2	0.0, 5.9
Min, Max	0.0, 7.5	0.0, 9.9
Change in Bone Pain at Week 12 from Baseline		
n	58	33
Mean (SD)	-0.2 (1.31)	0.2 (1.89)
Median	0.0	0.0
Q1, Q3	-0.8, 0.3	-0.4, 0.8
Min, Max	-3.7, 3.2	-4.4, 5.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Change from Baseline at Week 12		
n [1]	66	37
n [2]	58	33
MMRM: Least Squares Mean [SE] (95% CI)	-0.15 [0.22] (-0.59, 0.29)	0.23 [0.28] (-0.33, 0.79)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.38 [0.35] (-1.08, 0.31)	
MMRM: P-value	0.28	
Corrected Hedges' g (95% CI)	-0.229 (-0.657, 0.200)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.29	
Percent Change in Bone Pain at Week 12 from Baseline		
n	40	23
Mean (SD)	29.6 (196.28)	9.7 (83.65)
Median	-19.7	7.4
Q1, Q3	-53.8, 25.2	-64.3, 35.3
Min, Max	-100.0, 900.0	-100.0, 196.4
Difference in Percent Change from Baseline at Week 12		
n [1]	47	27
n [2]	40	23
MMRM: Least Squares Mean [SE] (95% CI)	31.84 [25.64] (-19.32, 83.01)	12.33 [33.49] (-54.51, 79.16)
MMRM: Least Squares Mean Difference [SE] (95% CI)	19.52 [41.84] (-63.97, 103.00)	
MMRM: P-value	0.64	
Corrected Hedges' g (95% CI)	0.119 (-0.394, 0.633)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.36	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Bone Pain at Week 16		
n	52	32
Mean (SD)	1.8 (2.06)	2.9 (3.35)
Median	1.0	1.2
Q1, Q3	0.0, 2.9	0.0, 5.8
Min, Max	0.0, 8.0	0.0, 9.5
Change in Bone Pain at Week 16 from Baseline		
n	52	32
Mean (SD)	-0.3 (1.41)	0.2 (1.86)
Median	0.0	0.0
Q1, Q3	-0.9, 0.2	-0.3, 0.5
Min, Max	-4.0, 3.7	-4.4, 4.4
Difference in Change from Baseline at Week 16		
n [1]	66	37
n [2]	52	32
MMRM: Least Squares Mean [SE] (95% CI)	-0.22 [0.23] (-0.67, 0.23)	0.23 [0.29] (-0.33, 0.80)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.46 [0.36] (-1.17, 0.25)	
MMRM: P-value	0.20	
Corrected Hedges' g (95% CI)	-0.279 (-0.721, 0.164)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.27	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Bone Pain at Week 16 from Baseline		
n	36	22
Mean (SD)	17.5 (160.86)	15.5 (88.18)
Median	-25.0	1.1
Q1, Q3	-53.2, 18.2	-25.0, 40.0
Min, Max	-100.0, 758.3	-100.0, 196.4
Difference in Percent Change from Baseline at Week 16		
n [1]	47	27
n [2]	36	22
MMRM: Least Squares Mean [SE] (95% CI)	31.18 [23.35] (-15.43, 77.78)	18.79 [30.23] (-41.52, 79.11)
MMRM: Least Squares Mean Difference [SE] (95% CI)	12.38 [37.85] (-63.15, 87.91)	
MMRM: P-value	0.74	
Corrected Hedges' g (95% CI)	0.087 (-0.444, 0.617)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.25	
Bone Pain at Week 20		
n	50	32
Mean (SD)	1.8 (2.07)	3.0 (3.24)
Median	1.1	1.2
Q1, Q3	0.0, 3.0	0.0, 6.1
Min, Max	0.0, 8.0	0.0, 9.4

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Bone Pain at Week 20 from Baseline		
n	50	32
Mean (SD)	-0.2 (1.36)	0.2 (1.86)
Median	0.0	0.0
Q1, Q3	-0.9, 0.4	-0.6, 1.4
Min, Max	-3.9, 3.8	-4.4, 4.2
Difference in Change from Baseline at Week 20		
n [1]	66	37
n [2]	50	32
MMRM: Least Squares Mean [SE] (95% CI)	-0.21 [0.23] (-0.66, 0.24)	0.28 [0.29] (-0.29, 0.85)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.49 [0.36] (-1.20, 0.22)	
MMRM: P-value	0.18	
Corrected Hedges' g (95% CI)	-0.299 (-0.745, 0.147)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.21	
Percent Change in Bone Pain at Week 20 from Baseline		
n	34	22
Mean (SD)	26.2 (172.88)	24.9 (94.44)
Median	-11.1	6.0
Q1, Q3	-49.1, 27.8	-28.6, 66.2
Min, Max	-100.0, 691.7	-100.0, 225.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 20		
n [1]	47	27
n [2]	34	22
MMRM: Least Squares Mean [SE] (95% CI)	29.03 [22.77] (-16.41, 74.47)	28.59 [29.25] (-29.77, 86.95)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.44 [36.74] (-72.87, 73.75)	
MMRM: P-value	0.99	
Corrected Hedges' g (95% CI)	0.003 (-0.533, 0.540)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.16	
Bone Pain at Week 24		
n	47	29
Mean (SD)	1.6 (1.92)	3.1 (3.17)
Median	1.1	1.5
Q1, Q3	0.0, 3.0	0.0, 6.2
Min, Max	0.0, 9.0	0.0, 9.1
Change in Bone Pain at Week 24 from Baseline		
n	47	29
Mean (SD)	-0.4 (1.68)	0.3 (1.97)
Median	0.0	0.0
Q1, Q3	-1.4, 0.3	0.0, 1.3
Min, Max	-4.6, 4.7	-4.4, 4.2

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Change from Baseline at Week 24		
n [1]	66	37
n [2]	47	29
MMRM: Least Squares Mean [SE] (95% CI)	-0.34 [0.26] (-0.85, 0.18)	0.29 [0.32] (-0.35, 0.94)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.63 [0.41] (-1.44, 0.18)	
MMRM: P-value	0.13	
Corrected Hedges' g (95% CI)	-0.354 (-0.821, 0.112)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.026	
Percent Change in Bone Pain at Week 24 from Baseline		
n	32	20
Mean (SD)	0.2 (144.92)	38.2 (109.87)
Median	-40.2	11.9
Q1, Q3	-68.8, 15.2	-16.5, 75.7
Min, Max	-100.0, 708.3	-100.0, 242.9
Difference in Percent Change from Baseline at Week 24		
n [1]	47	27
n [2]	32	20
MMRM: Least Squares Mean [SE] (95% CI)	25.02 [24.78] (-24.43, 74.48)	33.65 [31.89] (-29.99, 97.30)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-8.63 [40.10] (-88.65, 71.39)	
MMRM: P-value	0.83	
Corrected Hedges' g (95% CI)	-0.060 (-0.619, 0.499)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.015	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
TSS Item: Pain in Left Ribs		
Pain in Left Ribs at Baseline		
n	66	39
Mean (SD)	1.8 (2.22)	2.5 (2.68)
Median	0.9	2.0
Q1, Q3	0.0, 3.0	0.0, 3.9
Min, Max	0.0, 9.7	0.0, 8.8
Pain in Left Ribs at Week 4		
n	66	37
Mean (SD)	1.6 (1.93)	2.9 (3.10)
Median	1.1	2.3
Q1, Q3	0.0, 2.8	0.0, 5.0
Min, Max	0.0, 7.3	0.0, 10.0
Change in Pain in Left Ribs at Week 4 from Baseline		
n	66	37
Mean (SD)	-0.2 (1.08)	0.4 (1.47)
Median	0.0	0.0
Q1, Q3	-0.4, 0.2	-0.1, 0.8
Min, Max	-4.0, 2.1	-2.4, 4.7

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Change from Baseline at Week 4		
n [1]	66	37
n [2]	66	37
MMRM: Least Squares Mean [SE] (95% CI)	-0.27 [0.17] (-0.61, 0.07)	0.45 [0.21] (0.04, 0.86)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.73 [0.26] (-1.24, -0.22)	
MMRM: P-value	0.006	
Corrected Hedges' g (95% CI)	-0.536 (-0.945, -0.127)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.13	
Percent Change in Pain in Left Ribs at Week 4 from Baseline		
n	44	27
Mean (SD)	6.6 (99.19)	15.0 (98.69)
Median	-11.0	5.7
Q1, Q3	-39.5, 27.6	-24.0, 35.4
Min, Max	-100.0, 479.3	-100.0, 400.0
Difference in Percent Change from Baseline at Week 4		
n [1]	44	27
n [2]	44	27
MMRM: Least Squares Mean [SE] (95% CI)	3.48 [16.60] (-29.67, 36.62)	16.86 [19.53] (-22.14, 55.87)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-13.39 [25.41] (-64.13, 37.36)	
MMRM: P-value	0.60	
Corrected Hedges' g (95% CI)	-0.124 (-0.603, 0.356)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.25	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Pain in Left Ribs at Week 8		
n	59	35
Mean (SD)	1.2 (1.61)	2.9 (3.18)
Median	0.2	1.9
Q1, Q3	0.0, 2.3	0.1, 5.3
Min, Max	0.0, 6.8	0.0, 10.0
Change in Pain in Left Ribs at Week 8 from Baseline		
n	59	35
Mean (SD)	-0.5 (1.53)	0.4 (1.69)
Median	0.0	0.1
Q1, Q3	-0.9, 0.0	-0.6, 1.4
Min, Max	-6.1, 2.3	-3.3, 5.3
Difference in Change from Baseline at Week 8		
n [1]	66	37
n [2]	59	35
MMRM: Least Squares Mean [SE] (95% CI)	-0.49 [0.21] (-0.90, -0.07)	0.38 [0.26] (-0.13, 0.89)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.87 [0.32] (-1.51, -0.23)	
MMRM: P-value	0.008	
Corrected Hedges' g (95% CI)	-0.548 (-0.973, -0.122)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.009	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Pain in Left Ribs at Week 8 from Baseline		
n	38	26
Mean (SD)	5.2 (177.76)	25.5 (134.61)
Median	-36.3	4.2
Q1, Q3	-87.5, -1.3	-66.7, 37.5
Min, Max	-100.0, 875.0	-100.0, 451.0
Difference in Percent Change from Baseline at Week 8		
n [1]	44	27
n [2]	38	26
MMRM: Least Squares Mean [SE] (95% CI)	20.91 [27.58] (-34.18, 76.00)	27.90 [33.83] (-39.67, 95.47)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-6.99 [43.52] (-93.90, 79.92)	
MMRM: P-value	0.87	
Corrected Hedges' g (95% CI)	-0.040 (-0.539, 0.459)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.15	
Pain in Left Ribs at Week 12		
n	58	33
Mean (SD)	1.2 (1.60)	2.8 (3.13)
Median	0.7	1.4
Q1, Q3	0.0, 2.3	0.0, 4.4
Min, Max	0.0, 6.9	0.0, 10.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Pain in Left Ribs at Week 12 from Baseline		
n	58	33
Mean (SD)	-0.6 (1.67)	0.3 (1.56)
Median	0.0	0.0
Q1, Q3	-0.9, 0.1	-0.7, 1.2
Min, Max	-6.3, 1.9	-2.7, 4.5
Difference in Change from Baseline at Week 12		
n [1]	66	37
n [2]	58	33
MMRM: Least Squares Mean [SE] (95% CI)	-0.59 [0.21] (-1.02, -0.16)	0.27 [0.27] (-0.27, 0.80)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.86 [0.33] (-1.52, -0.19)	
MMRM: P-value	0.012	
Corrected Hedges' g (95% CI)	-0.530 (-0.964, -0.095)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.040	
Percent Change in Pain in Left Ribs at Week 12 from Baseline		
n	38	24
Mean (SD)	-3.5 (146.72)	51.3 (202.54)
Median	-44.2	6.7
Q1, Q3	-95.2, 12.2	-41.4, 50.1
Min, Max	-100.0, 700.0	-100.0, 850.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 12		
n [1]	44	27
n [2]	38	24
MMRM: Least Squares Mean [SE] (95% CI)	5.31 [27.26] (-49.12, 59.75)	51.13 [33.64] (-16.05, 118.31)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-45.82 [43.16] (-132.02, 40.39)	
MMRM: P-value	0.29	
Corrected Hedges' g (95% CI)	-0.271 (-0.785, 0.242)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.084	
Pain in Left Ribs at Week 16		
n	52	32
Mean (SD)	1.2 (1.69)	2.8 (3.17)
Median	0.2	1.6
Q1, Q3	0.0, 2.1	0.0, 4.6
Min, Max	0.0, 7.0	0.0, 9.9
Change in Pain in Left Ribs at Week 16 from Baseline		
n	52	32
Mean (SD)	-0.7 (1.74)	0.4 (1.71)
Median	-0.1	0.0
Q1, Q3	-1.4, 0.1	-0.8, 1.2
Min, Max	-6.3, 1.9	-2.6, 5.8

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Change from Baseline at Week 16		
n [1]	66	37
n [2]	52	32
MMRM: Least Squares Mean [SE] (95% CI)	-0.59 [0.22] (-1.03, -0.14)	0.43 [0.28] (-0.13, 0.99)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.02 [0.35] (-1.72, -0.32)	
MMRM: P-value	0.005	
Corrected Hedges' g (95% CI)	-0.627 (-1.078, -0.177)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.020	
Percent Change in Pain in Left Ribs at Week 16 from Baseline		
n	36	23
Mean (SD)	-4.7 (167.41)	72.4 (269.05)
Median	-62.0	1.4
Q1, Q3	-100.0, 7.5	-47.2, 40.0
Min, Max	-100.0, 650.0	-100.0, 1150.0
Difference in Percent Change from Baseline at Week 16		
n [1]	44	27
n [2]	36	23
MMRM: Least Squares Mean [SE] (95% CI)	-0.41 [31.82] (-63.95, 63.13)	73.59 [39.84] (-5.97, 153.14)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-73.99 [50.90] (-175.64, 27.66)	
MMRM: P-value	0.15	
Corrected Hedges' g (95% CI)	-0.382 (-0.910, 0.145)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.007	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Pain in Left Ribs at Week 20			
n	50	32	
Mean (SD)	1.1 (1.64)	3.0 (3.17)	
Median	0.1	2.0	
Q1, Q3	0.0, 2.0	0.0, 4.8	
Min, Max	0.0, 6.8	0.0, 10.0	
Change in Pain in Left Ribs at Week 20 from Baseline			
n	50	32	
Mean (SD)	-0.6 (1.67)	0.6 (1.81)	
Median	-0.1	0.2	
Q1, Q3	-1.5, 0.0	-0.7, 1.6	
Min, Max	-6.3, 2.4	-2.3, 4.7	
Difference in Change from Baseline at Week 20			
n [1]	66	37	
n [2]	50	32	
MMRM: Least Squares Mean [SE] (95% CI)	-0.64 [0.24] (-1.11, -0.17)	0.56 [0.30] (-0.03, 1.15)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.20 [0.37] (-1.94, -0.47)		
MMRM: P-value	0.002		
Corrected Hedges' g (95% CI)	-0.709 (-1.166, -0.252)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.007		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in Pain in Left Ribs at Week 20 from Baseline			
n	34	23	
Mean (SD)	2.5 (187.04)	85.9 (296.67)	
Median	-50.7	9.1	
Q1, Q3	-100.0, -7.6	-62.5, 62.8	
Min, Max	-100.0, 700.0	-100.0, 1275.0	
Difference in Percent Change from Baseline at Week 20			
n [1]	44	27	
n [2]	34	23	
MMRM: Least Squares Mean [SE] (95% CI)	3.94 [35.58] (-67.13, 75.00)	86.39 [44.38] (-2.24, 175.02)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-82.45 [56.80] (-195.89, 30.99)		
MMRM: P-value	0.15		
Corrected Hedges' g (95% CI)	-0.388 (-0.922, 0.146)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.014		
Pain in Left Ribs at Week 24			
n	47	29	
Mean (SD)	1.0 (1.50)	3.2 (3.30)	
Median	0.2	2.3	
Q1, Q3	0.0, 1.6	0.0, 5.4	
Min, Max	0.0, 6.2	0.0, 10.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Pain in Left Ribs at Week 24 from Baseline		
n	47	29
Mean (SD)	-0.7 (1.61)	0.8 (1.85)
Median	0.0	0.5
Q1, Q3	-1.7, 0.0	-0.3, 1.5
Min, Max	-6.3, 2.2	-2.2, 6.2
Difference in Change from Baseline at Week 24		
n [1]	66	37
n [2]	47	29
MMRM: Least Squares Mean [SE] (95% CI)	-0.61 [0.24] (-1.08, -0.15)	0.63 [0.29] (0.04, 1.21)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.24 [0.37] (-1.97, -0.51)	
MMRM: P-value	0.001	
Corrected Hedges' g (95% CI)	-0.766 (-1.245, -0.288)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	< 0.001	
Percent Change in Pain in Left Ribs at Week 24 from Baseline		
n	33	21
Mean (SD)	0.4 (160.61)	107.7 (311.91)
Median	-56.0	20.8
Q1, Q3	-95.6, 2.3	-16.2, 50.0
Min, Max	-100.0, 600.0	-100.0, 1300.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 24		
n [1]	44	27
n [2]	33	21
MMRM: Least Squares Mean [SE] (95% CI)	0.67 [33.78] (-66.79, 68.13)	94.26 [42.20] (9.98, 178.54)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-93.59 [53.95] (-201.34, 14.16)	
MMRM: P-value	0.088	
Corrected Hedges' g (95% CI)	-0.476 (-1.030, 0.078)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.003	
TSS Item: Inactivity		
Inactivity at Baseline		
n	66	39
Mean (SD)	3.7 (2.50)	4.4 (3.05)
Median	3.3	4.1
Q1, Q3	1.9, 5.5	1.6, 7.0
Min, Max	0.0, 8.6	0.0, 9.9
Inactivity at Week 4		
n	66	37
Mean (SD)	3.8 (2.31)	4.5 (3.05)
Median	3.6	4.1
Q1, Q3	2.1, 5.2	2.3, 7.3
Min, Max	0.0, 9.5	0.0, 9.7

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Inactivity at Week 4 from Baseline		
n	66	37
Mean (SD)	0.1 (1.38)	0.1 (1.34)
Median	0.0	0.1
Q1, Q3	-0.5, 0.7	-0.3, 0.5
Min, Max	-3.6, 3.4	-4.4, 2.6
Difference in Change from Baseline at Week 4		
n [1]	66	37
n [2]	66	37
MMRM: Least Squares Mean [SE] (95% CI)	0.18 [0.18] (-0.18, 0.53)	0.20 [0.22] (-0.23, 0.63)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.02 [0.27] (-0.56, 0.51)	
MMRM: P-value	0.93	
Corrected Hedges' g (95% CI)	-0.018 (-0.420, 0.385)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.99	
Percent Change in Inactivity at Week 4 from Baseline		
n	63	33
Mean (SD)	21.1 (68.28)	19.5 (74.19)
Median	0.2	2.9
Q1, Q3	-16.8, 32.3	-8.3, 11.6
Min, Max	-59.3, 341.4	-100.0, 258.6

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 4		
n [1]	63	33
n [2]	63	33
MMRM: Least Squares Mean [SE] (95% CI)	24.38 [8.94] (6.62, 42.14)	31.83 [11.22] (9.54, 54.13)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-7.45 [13.72] (-34.71, 19.80)	
MMRM: P-value	0.59	
Corrected Hedges' g (95% CI)	-0.107 (-0.529, 0.314)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.91	
Inactivity at Week 8		
n	59	35
Mean (SD)	3.5 (2.18)	4.5 (2.97)
Median	3.1	4.6
Q1, Q3	1.9, 5.4	2.7, 6.8
Min, Max	0.0, 7.2	0.0, 10.0
Change in Inactivity at Week 8 from Baseline		
n	59	35
Mean (SD)	-0.1 (1.90)	0.1 (1.35)
Median	-0.1	0.0
Q1, Q3	-1.1, 0.9	-0.6, 0.8
Min, Max	-5.0, 5.1	-3.2, 2.6

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Change from Baseline at Week 8		
n [1]	66	37
n [2]	59	35
MMRM: Least Squares Mean [SE] (95% CI)	0.07 [0.22] (-0.37, 0.51)	0.35 [0.27] (-0.19, 0.89)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.28 [0.34] (-0.96, 0.40)	
MMRM: P-value	0.41	
Corrected Hedges' g (95% CI)	-0.166 (-0.585, 0.252)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.25	
Percent Change in Inactivity at Week 8 from Baseline		
n	56	31
Mean (SD)	14.3 (88.86)	30.1 (126.50)
Median	-5.4	5.6
Q1, Q3	-30.2, 36.8	-8.7, 20.8
Min, Max	-100.0, 511.1	-100.0, 625.9
Difference in Percent Change from Baseline at Week 8		
n [1]	63	33
n [2]	56	31
MMRM: Least Squares Mean [SE] (95% CI)	27.88 [14.49] (-0.91, 56.67)	51.86 [19.26] (13.60, 90.11)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-23.98 [23.74] (-71.15, 23.19)	
MMRM: P-value	0.32	
Corrected Hedges' g (95% CI)	-0.220 (-0.660, 0.220)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.25	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Inactivity at Week 12		
n	58	33
Mean (SD)	3.4 (2.25)	4.8 (3.11)
Median	3.1	4.9
Q1, Q3	2.0, 4.9	3.1, 7.4
Min, Max	0.0, 8.9	0.0, 10.0
Change in Inactivity at Week 12 from Baseline		
n	58	33
Mean (SD)	-0.3 (2.05)	0.3 (1.64)
Median	-0.1	0.2
Q1, Q3	-1.1, 0.6	-0.4, 1.1
Min, Max	-6.3, 5.0	-3.3, 5.6
Difference in Change from Baseline at Week 12		
n [1]	66	37
n [2]	58	33
MMRM: Least Squares Mean [SE] (95% CI)	0.02 [0.25] (-0.48, 0.51)	0.63 [0.32] (0.00, 1.25)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.61 [0.39] (-1.39, 0.17)	
MMRM: P-value	0.12	
Corrected Hedges' g (95% CI)	-0.323 (-0.753, 0.107)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.12	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Inactivity at Week 12 from Baseline		
n	55	29
Mean (SD)	9.8 (82.98)	78.3 (365.91)
Median	-5.3	5.0
Q1, Q3	-36.4, 45.2	-9.2, 36.3
Min, Max	-100.0, 357.1	-100.0, 1948.1
Difference in Percent Change from Baseline at Week 12		
n [1]	63	33
n [2]	55	29
MMRM: Least Squares Mean [SE] (95% CI)	39.58 [32.95] (-25.88, 105.05)	107.34 [44.97] (18.00, 196.67)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-67.75 [55.61] (-178.22, 42.72)	
MMRM: P-value	0.23	
Corrected Hedges' g (95% CI)	-0.276 (-0.727, 0.176)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.29	
Inactivity at Week 16		
n	52	32
Mean (SD)	3.3 (2.20)	4.6 (3.20)
Median	3.0	4.4
Q1, Q3	1.7, 4.8	2.7, 7.4
Min, Max	0.0, 8.6	0.0, 9.9

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Inactivity at Week 16 from Baseline		
n	52	32
Mean (SD)	-0.3 (2.15)	0.1 (1.45)
Median	-0.2	0.1
Q1, Q3	-1.2, 0.3	-0.6, 0.8
Min, Max	-7.4, 6.2	-4.3, 3.0
Difference in Change from Baseline at Week 16		
n [1]	66	37
n [2]	52	32
MMRM: Least Squares Mean [SE] (95% CI)	-0.01 [0.26] (-0.51, 0.50)	0.44 [0.32] (-0.20, 1.08)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.45 [0.40] (-1.25, 0.35)	
MMRM: P-value	0.27	
Corrected Hedges' g (95% CI)	-0.241 (-0.683, 0.201)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.061	
Percent Change in Inactivity at Week 16 from Baseline		
n	49	28
Mean (SD)	96.2 (627.08)	36.9 (153.08)
Median	-12.3	4.5
Q1, Q3	-37.5, 12.5	-11.5, 21.4
Min, Max	-89.2, 4350.0	-100.0, 737.5

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 16		
n [1]	63	33
n [2]	49	28
MMRM: Least Squares Mean [SE] (95% CI)	103.96 [66.47] (-28.10, 236.03)	65.53 [89.72] (-112.71, 243.76)
MMRM: Least Squares Mean Difference [SE] (95% CI)	38.44 [111.55] (-183.17, 260.05)	
MMRM: P-value	0.73	
Corrected Hedges' g (95% CI)	0.081 (-0.383, 0.546)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.050	
Inactivity at Week 20		
n	50	32
Mean (SD)	3.4 (2.28)	4.7 (3.34)
Median	3.2	4.6
Q1, Q3	1.3, 5.3	2.0, 7.5
Min, Max	0.0, 8.7	0.0, 10.0
Change in Inactivity at Week 20 from Baseline		
n	50	32
Mean (SD)	-0.3 (2.29)	0.1 (1.73)
Median	0.0	0.0
Q1, Q3	-1.7, 0.9	-0.6, 0.6
Min, Max	-7.2, 6.4	-4.4, 5.2

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Change from Baseline at Week 20		
n [1]	66	37
n [2]	50	32
MMRM: Least Squares Mean [SE] (95% CI)	0.01 [0.28] (-0.54, 0.56)	0.47 [0.35] (-0.22, 1.17)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.46 [0.44] (-1.33, 0.41)	
MMRM: P-value	0.30	
Corrected Hedges' g (95% CI)	-0.231 (-0.677, 0.214)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.17	
Percent Change in Inactivity at Week 20 from Baseline		
n	47	28
Mean (SD)	104.4 (652.28)	23.2 (87.74)
Median	0.0	2.2
Q1, Q3	-39.9, 33.0	-11.4, 30.4
Min, Max	-100.0, 4450.0	-100.0, 322.2
Difference in Percent Change from Baseline at Week 20		
n [1]	63	33
n [2]	47	28
MMRM: Least Squares Mean [SE] (95% CI)	106.01 [67.81] (-28.71, 240.74)	50.18 [91.33] (-131.27, 231.63)
MMRM: Least Squares Mean Difference [SE] (95% CI)	55.83 [113.64] (-169.92, 281.59)	
MMRM: P-value	0.62	
Corrected Hedges' g (95% CI)	0.117 (-0.351, 0.585)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.092	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Inactivity at Week 24		
n	47	29
Mean (SD)	3.1 (2.32)	5.0 (3.30)
Median	2.8	4.8
Q1, Q3	1.1, 5.0	3.0, 7.9
Min, Max	0.0, 7.9	0.0, 10.0
Change in Inactivity at Week 24 from Baseline		
n	47	29
Mean (SD)	-0.5 (2.63)	0.2 (1.88)
Median	0.0	0.1
Q1, Q3	-2.0, 0.7	-0.7, 1.1
Min, Max	-8.2, 6.1	-4.4, 5.2
Difference in Change from Baseline at Week 24		
n [1]	66	37
n [2]	47	29
MMRM: Least Squares Mean [SE] (95% CI)	-0.08 [0.31] (-0.69, 0.54)	0.50 [0.39] (-0.27, 1.28)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.58 [0.49] (-1.55, 0.40)	
MMRM: P-value	0.24	
Corrected Hedges' g (95% CI)	-0.271 (-0.735, 0.194)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.16	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1901: Analysis of TSS Items at Every 4 weeks and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Inactivity at Week 24 from Baseline		
n	44	26
Mean (SD)	102.7 (652.10)	32.4 (93.67)
Median	2.5	3.3
Q1, Q3	-48.5, 53.3	-12.7, 53.5
Min, Max	-100.0, 4300.0	-100.0, 387.5
Difference in Percent Change from Baseline at Week 24		
n [1]	63	33
n [2]	44	26
MMRM: Least Squares Mean [SE] (95% CI)	100.98 [65.56] (-29.26, 231.23)	54.40 [88.27] (-120.97, 229.78)
MMRM: Least Squares Mean Difference [SE] (95% CI)	46.58 [109.83] (-171.61, 264.77)	
MMRM: P-value	0.67	
Corrected Hedges' g (95% CI)	0.105 (-0.381, 0.590)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.092	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more timepoints.
[2] Number of subjects with analysable data at the current timepoint.

Data Extracted: CRF data: 25JUN2019

Table 2.1501: Analysis of TSS, Change and % Change from Baseline by Every 4 weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Average Daily Total Symptom Score at Baseline		
n	66	39
Mean (SD)	16.7 (11.23)	20.7 (15.72)
Median	14.1	16.7
Q1, Q3	8.5, 23.7	7.4, 30.0
Min, Max	0.0, 53.0	0.0, 55.5
Average Daily Total Symptom Score at Week 4		
n	66	37
Mean (SD)	15.9 (11.70)	21.5 (16.63)
Median	12.7	17.4
Q1, Q3	6.9, 22.3	7.8, 35.1
Min, Max	0.4, 49.5	0.0, 56.6
Change in Average Daily Total Symptom Score at Week 4 from Baseline		
n	66	37
Mean (SD)	-0.8 (6.03)	0.5 (6.83)
Median	-0.6	1.3
Q1, Q3	-4.4, 2.5	-0.5, 3.1
Min, Max	-19.1, 15.2	-19.9, 19.5

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.1501: Analysis of TSS, Change and % Change from Baseline by Every 4 weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	66	37	
n [2]	66	37	
MMRM: Least Squares Mean [SE] (95% CI)	-0.57 [0.89] (-2.34, 1.20)	0.89 [1.09] (-1.26, 3.05)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.46 [1.34] (-4.11, 1.19)		
MMRM: P-value	0.28		
Corrected Hedges' g (95% CI)	-0.207 (-0.610, 0.197)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.099		
Percent Change in Average Daily Total Symptom Score at Week 4 from Baseline			
n	65	34	
Mean (SD)	0.4 (46.32)	25.5 (89.40)	
Median	-8.8	4.6	
Q1, Q3	-25.3, 19.9	-3.3, 22.7	
Min, Max	-87.9, 145.1	-91.5, 450.9	
Difference in Percent Change from Baseline at Week 4			
n [1]	65	34	
n [2]	65	34	
MMRM: Least Squares Mean [SE] (95% CI)	-2.83 [8.95] (-20.61, 14.94)	31.28 [11.19] (9.06, 53.50)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-34.11 [13.71] (-61.34, -6.89)		
MMRM: P-value	0.015		
Corrected Hedges' g (95% CI)	-0.484 (-0.905, -0.064)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.092		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.1501: Analysis of TSS, Change and % Change from Baseline by Every 4 weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Average Daily Total Symptom Score at Week 8		
n	59	35
Mean (SD)	13.4 (9.46)	21.6 (17.45)
Median	12.2	18.3
Q1, Q3	5.4, 20.6	6.8, 30.8
Min, Max	0.1, 41.5	0.0, 60.4
Change in Average Daily Total Symptom Score at Week 8 from Baseline		
n	59	35
Mean (SD)	-2.8 (7.52)	0.3 (8.32)
Median	-2.1	0.5
Q1, Q3	-7.5, 2.5	-3.6, 6.1
Min, Max	-20.9, 13.0	-23.8, 22.4
Difference in Change from Baseline at Week 8		
n [1]	66	37
n [2]	59	35
MMRM: Least Squares Mean [SE] (95% CI)	-1.68 [1.07] (-3.80, 0.44)	0.98 [1.34] (-1.69, 3.64)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.65 [1.66] (-5.95, 0.64)	
MMRM: P-value	0.11	
Corrected Hedges' g (95% CI)	-0.325 (-0.746, 0.096)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.030	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-tss-spleen.sas V.03.05 Output file: t-chg-tss-rt-gba.pdf 24AUG2023:17:05

Table 2.1501: Analysis of TSS, Change and % Change from Baseline by Every 4 weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Average Daily Total Symptom Score at Week 8 from Baseline		
n	58	32
Mean (SD)	-8.2 (58.17)	20.8 (83.19)
Median	-24.7	4.3
Q1, Q3	-45.7, 21.4	-16.5, 20.8
Min, Max	-88.2, 160.9	-85.9, 321.1
Difference in Percent Change from Baseline at Week 8		
n [1]	65	34
n [2]	58	32
MMRM: Least Squares Mean [SE] (95% CI)	-8.20 [9.34] (-26.75, 10.34)	29.21 [11.70] (5.98, 52.43)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-37.41 [14.37] (-65.94, -8.88)	
MMRM: P-value	0.011	
Corrected Hedges' g (95% CI)	-0.534 (-0.973, -0.096)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.040	
Average Daily Total Symptom Score at Week 12		
n	58	33
Mean (SD)	12.6 (9.61)	21.6 (17.58)
Median	12.0	20.2
Q1, Q3	5.1, 18.4	6.9, 29.8
Min, Max	0.0, 43.1	0.0, 63.5

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.1501: Analysis of TSS, Change and % Change from Baseline by Every 4 weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Average Daily Total Symptom Score at Week 12 from Baseline		
n	58	33
Mean (SD)	-3.9 (8.05)	0.4 (8.44)
Median	-2.4	0.5
Q1, Q3	-9.0, 2.2	-1.3, 6.6
Min, Max	-23.8, 10.5	-24.3, 13.2
Difference in Change from Baseline at Week 12		
n [1]	66	37
n [2]	58	33
MMRM: Least Squares Mean [SE] (95% CI)	-2.72 [1.15] (-5.00, -0.44)	1.34 [1.45] (-1.54, 4.23)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-4.07 [1.80] (-7.64, -0.49)	
MMRM: P-value	0.026	
Corrected Hedges' g (95% CI)	-0.468 (-0.901, -0.036)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.011	
Percent Change in Average Daily Total Symptom Score at Week 12 from Baseline		
n	57	30
Mean (SD)	-17.6 (54.33)	33.8 (116.30)
Median	-27.3	4.6
Q1, Q3	-57.0, 17.0	-12.5, 26.1
Min, Max	-100.0, 153.7	-100.0, 435.8

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.1501: Analysis of TSS, Change and % Change from Baseline by Every 4 weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 12		
n [1]	65	34
n [2]	57	30
MMRM: Least Squares Mean [SE] (95% CI)	-16.81 [10.89] (-38.43, 4.81)	42.43 [14.00] (14.64, 70.22)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-59.24 [17.22] (-93.43, -25.05)	
MMRM: P-value	< 0.001	
Corrected Hedges' g (95% CI)	-0.731 (-1.186, -0.275)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.006	
Average Daily Total Symptom Score at Week 16		
n	52	32
Mean (SD)	11.9 (9.86)	22.1 (18.18)
Median	10.7	20.7
Q1, Q3	3.9, 17.1	6.4, 30.3
Min, Max	0.0, 42.8	0.0, 65.1
Change in Average Daily Total Symptom Score at Week 16 from Baseline		
n	52	32
Mean (SD)	-4.5 (8.53)	0.8 (8.58)
Median	-2.6	1.7
Q1, Q3	-7.7, 0.5	-1.5, 6.2
Min, Max	-25.0, 9.6	-22.2, 15.2

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.1501: Analysis of TSS, Change and % Change from Baseline by Every 4 weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	66	37	
n [2]	52	32	
MMRM: Least Squares Mean [SE] (95% CI)	-2.70 [1.21] (-5.11, -0.29)	2.06 [1.55] (-1.01, 5.13)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-4.76 [1.92] (-8.57, -0.96)		
MMRM: P-value	0.015		
Corrected Hedges' g (95% CI)	-0.539 (-0.987, -0.091)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.001		
Percent Change in Average Daily Total Symptom Score at Week 16 from Baseline			
n	51	29	
Mean (SD)	-17.0 (60.53)	32.8 (114.74)	
Median	-25.1	12.8	
Q1, Q3	-58.7, 6.6	-16.3, 22.9	
Min, Max	-90.9, 205.4	-100.0, 443.3	
Difference in Percent Change from Baseline at Week 16			
n [1]	65	34	
n [2]	51	29	
MMRM: Least Squares Mean [SE] (95% CI)	-12.86 [11.13] (-34.97, 9.25)	42.35 [14.28] (14.00, 70.71)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-55.21 [17.61] (-90.18, -20.25)		
MMRM: P-value	0.002		
Corrected Hedges' g (95% CI)	-0.696 (-1.164, -0.227)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	<0.001		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.1501: Analysis of TSS, Change and % Change from Baseline by Every 4 weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Average Daily Total Symptom Score at Week 20		
n	50	32
Mean (SD)	11.4 (9.75)	21.9 (18.30)
Median	9.4	18.6
Q1, Q3	4.9, 15.4	6.1, 32.5
Min, Max	0.0, 45.2	0.0, 64.7
Change in Average Daily Total Symptom Score at Week 20 from Baseline		
n	50	32
Mean (SD)	-4.5 (8.88)	0.6 (9.45)
Median	-2.7	1.0
Q1, Q3	-7.8, 1.0	-3.6, 6.4
Min, Max	-25.0, 10.5	-22.7, 21.9
Difference in Change from Baseline at Week 20		
n [1]	66	37
n [2]	50	32
MMRM: Least Squares Mean [SE] (95% CI)	-3.04 [1.30] (-5.63, -0.46)	1.89 [1.67] (-1.42, 5.19)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-4.93 [2.07] (-9.04, -0.82)	
MMRM: P-value	0.019	
Corrected Hedges' g (95% CI)	-0.526 (-0.977, -0.075)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.003	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-tss-spleen.sas V.03.05 Output file: t-chg-tss-rt-gba.pdf 24AUG2023:17:05

Table 2.1501: Analysis of TSS, Change and % Change from Baseline by Every 4 weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Average Daily Total Symptom Score at Week 20 from Baseline		
n	49	29
Mean (SD)	-8.0 (97.07)	32.9 (120.35)
Median	-31.7	8.5
Q1, Q3	-63.0, 7.2	-26.1, 29.6
Min, Max	-100.0, 432.1	-100.0, 495.0
Difference in Percent Change from Baseline at Week 20		
n [1]	65	34
n [2]	49	29
MMRM: Least Squares Mean [SE] (95% CI)	-3.75 [13.74] (-31.04, 23.54)	42.58 [17.92] (7.00, 78.16)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-46.33 [22.21] (-90.44, -2.22)	
MMRM: P-value	0.040	
Corrected Hedges' g (95% CI)	-0.476 (-0.942, -0.011)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.001	
Average Daily Total Symptom Score at Week 24		
n	47	29
Mean (SD)	10.5 (8.62)	23.6 (18.52)
Median	8.3	19.6
Q1, Q3	4.3, 14.7	8.3, 36.3
Min, Max	0.0, 34.5	0.0, 62.7

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.1501: Analysis of TSS, Change and % Change from Baseline by Every 4 weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in Average Daily Total Symptom Score at Week 24 from Baseline		
n	47	29
Mean (SD)	-5.1 (9.34)	2.0 (9.00)
Median	-5.0	2.1
Q1, Q3	-9.5, 2.3	-2.9, 6.0
Min, Max	-29.4, 11.7	-20.1, 23.6
Difference in Change from Baseline at Week 24		
n [1]	66	37
n [2]	47	29
MMRM: Least Squares Mean [SE] (95% CI)	-3.30 [1.35] (-5.98, -0.63)	2.30 [1.72] (-1.12, 5.71)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-5.60 [2.15] (-9.86, -1.34)	
MMRM: P-value	0.011	
Corrected Hedges' g (95% CI)	-0.599 (-1.071, -0.126)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	<0.001	
Percent Change in Average Daily Total Symptom Score at Week 24 from Baseline		
n	46	27
Mean (SD)	-7.8 (111.51)	47.3 (150.18)
Median	-47.9	12.0
Q1, Q3	-62.5, 9.4	-14.9, 26.7
Min, Max	-98.4, 563.0	-99.3, 696.7

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.1501: Analysis of TSS, Change and % Change from Baseline by Every 4 weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	65	34	
n [2]	46	27	
MMRM: Least Squares Mean [SE] (95% CI)	-1.54 [16.34] (-33.99, 30.90)	49.19 [21.38] (6.73, 91.66)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-50.74 [26.61] (-103.58, 2.10)		
MMRM: P-value	0.060		
Corrected Hedges' g (95% CI)	-0.453 (-0.933, 0.028)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	<0.001		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18), Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

GSK Oncology

Study GS-US-352-1214

Table 2.1418: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Inactivity) by Every 4 Weeks

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Inactivity Symptom Score Status			
Missing Inactivity Score at baseline (excluded from rate calculation)	0	0	0
Inactivity Score = 0 at baseline	3 (4.5%)	4 (10.3%)	7 (6.7%)
Inactivity Score > 0 at baseline	63 (95.5%)	35 (89.7%)	98 (93.3%)
Response Rate of Inactivity Symptom Score at Week 4			
Subjects Evaluable at Week 4, n	63	35	98
Inactivity Score = 0 at baseline and Inactivity Score >0 or missing at Week 4	0	0	0
Responder, n(%)	4 (6.3%)	3 (8.6%)	7 (7.1%)
95% Exact CI	0.0176, 0.1547	0.0180, 0.2306	0.0292, 0.1416
Proportion Difference - Stratified CMH Method (95% CI)	-0.03 (-0.17, 0.10)		
p-value	0.62		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.02 (-0.14, 0.10)		
p-value	0.71		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.02 (-0.23, 0.18)		
p-value	0.70		
Unadjusted Inverse Relative Risk (95% CI)	1.35 (0.32, 5.69)		
p-value [1]	0.68		
Unadjusted Inverse Odds Ratio (95% CI)	1.38 (0.29, 6.56)		
p-value [1]	0.68		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.13, 0.09)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

GSK Oncology
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Table 2.1418: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Inactivity) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	59 (93.7%)	32 (91.4%)	91 (92.9%)
Last participation date < Day 21 in RT Phase	0	2 (5.7%)	2 (2.0%)
Last participation date >= Day 21 and Inactivity Score at Week 4 not available	0	0	0
>0% increase from baseline at Week 4	32 (50.8%)	20 (57.1%)	52 (53.1%)
<50% reduction from baseline at Week 4	59 (93.7%)	30 (85.7%)	89 (90.8%)
Return Rate (%)	100%	95%	98%
Number of Subjects in Risk	66	37	103
Return Rate in Risk (%)	100%	100%	100%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

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Table 2.1418: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Inactivity) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Inactivity Symptom Score at Week 8			
Subjects Evaluable at Week 8, n	63	35	98
Inactivity Score = 0 at baseline and Inactivity Score >0 or missing at Week 8	0	0	0
Responder, n(%)	7 (11.1%)	3 (8.6%)	10 (10.2%)
95% Exact CI	0.0459, 0.2156	0.0180, 0.2306	0.0500, 0.1797
Proportion Difference - Stratified CMH Method (95% CI)	0.02 (-0.13, 0.16)		
p-value	0.84		
Proportion Difference - Unstratified CMH Method (95% CI)	0.03 (-0.10, 0.15)		
p-value	0.70		
Proportion Difference - Unstratified Exact Method (95% CI)	0.03 (-0.18, 0.23)		
p-value	1.00		
Unadjusted Inverse Relative Risk (95% CI)	0.77 (0.21, 2.80)		
p-value [1]	0.69		
Unadjusted Inverse Odds Ratio (95% CI)	0.75 (0.18, 3.10)		
p-value [1]	0.69		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.10, 0.15)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

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Table 2.1418: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Inactivity) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	56 (88.9%)	32 (91.4%)	88 (89.8%)
Last participation date < Day 50 in RT Phase	5 (7.9%)	3 (8.6%)	8 (8.2%)
Last participation date >= Day 50 and Inactivity Score at Week 8 not available	2 (3.2%)	1 (2.9%)	3 (3.1%)
>0% increase from baseline at Week 8	25 (39.7%)	17 (48.6%)	42 (42.9%)
<50% reduction from baseline at Week 8	49 (77.8%)	28 (80.0%)	77 (78.6%)
Return Rate (%)	89%	90%	90%
Number of Subjects in Risk	61	36	97
Return Rate in Risk (%)	97%	97%	97%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

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Table 2.1418: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Inactivity) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Inactivity Symptom Score at Week 12			
Subjects Evaluable at Week 12, n	63	35	98
Inactivity Score = 0 at baseline and Inactivity Score >0 or missing at Week 12	0	0	0
Responder, n(%)	11 (17.5%)	3 (8.6%)	14 (14.3%)
95% Exact CI	0.0905, 0.2910	0.0180, 0.2306	0.0804, 0.2281
Proportion Difference - Stratified CMH Method (95% CI)	0.08 (-0.08, 0.24)		
p-value	0.30		
Proportion Difference - Unstratified CMH Method (95% CI)	0.09 (-0.05, 0.23)		
p-value	0.21		
Proportion Difference - Unstratified Exact Method (95% CI)	0.09 (-0.12, 0.29)		
p-value	0.37		
Unadjusted Inverse Relative Risk (95% CI)	0.49 (0.15, 1.64)		
p-value [1]	0.25		
Unadjusted Inverse Odds Ratio (95% CI)	0.44 (0.11, 1.71)		
p-value [1]	0.24		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.04, 0.22)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.51 (0.15, 1.74)		
p-value [2]	0.28		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

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Table 2.1418: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Inactivity) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	52 (82.5%)	32 (91.4%)	84 (85.7%)
Last participation date < Day 78 in RT Phase	7 (11.1%)	6 (17.1%)	13 (13.3%)
Last participation date >= Day 78 and Inactivity Score at Week 12 not available	2 (3.2%)	0	2 (2.0%)
>0% increase from baseline at Week 12	22 (34.9%)	18 (51.4%)	40 (40.8%)
<50% reduction from baseline at Week 12	43 (68.3%)	26 (74.3%)	69 (70.4%)
Return Rate (%)	86%	85%	86%
Number of Subjects in Risk	59	33	92
Return Rate in Risk (%)	97%	100%	98%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

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Table 2.1418: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Inactivity) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Inactivity Symptom Score at Week 16			
Subjects Evaluable at Week 16, n	64	35	99
Inactivity Score = 0 at baseline and Inactivity Score >0 or missing at Week 16	1 (1.6%)	0	1 (1.0%)
Responder, n(%)	10 (15.6%)	2 (5.7%)	12 (12.1%)
95% Exact CI	0.0776, 0.2686	0.0070, 0.1916	0.0642, 0.2022
Proportion Difference - Stratified CMH Method (95% CI)	0.10 (-0.04, 0.25)		
p-value	0.17		
Proportion Difference - Unstratified CMH Method (95% CI)	0.10 (-0.03, 0.22)		
p-value	0.12		
Proportion Difference - Unstratified Exact Method (95% CI)	0.10 (-0.11, 0.30)		
p-value	0.20		
Unadjusted Inverse Relative Risk (95% CI)	0.37 (0.08, 1.58)		
p-value [1]	0.18		
Unadjusted Inverse Odds Ratio (95% CI)	0.33 (0.07, 1.59)		
p-value [1]	0.17		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.02, 0.22)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.35 (0.08, 1.51)		
p-value [2]	0.16		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

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Table 2.1418: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Inactivity) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	54 (84.4%)	33 (94.3%)	87 (87.9%)
Last participation date < Day 106 in RT Phase	10 (15.6%)	7 (20.0%)	17 (17.2%)
Last participation date >= Day 106 and Inactivity Score at Week 16 not available	4 (6.3%)	0	4 (4.0%)
>0% increase from baseline at Week 16	17 (26.6%)	17 (48.6%)	34 (34.3%)
<50% reduction from baseline at Week 16	39 (60.9%)	26 (74.3%)	65 (65.7%)
Return Rate (%)	79%	82%	80%
Number of Subjects in Risk	56	32	88
Return Rate in Risk (%)	93%	100%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

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Table 2.1418: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Inactivity) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Inactivity Symptom Score at Week 20			
Subjects Evaluable at Week 20, n	63	35	98
Inactivity Score = 0 at baseline and Inactivity Score >0 or missing at Week 20	0	0	0
Responder, n(%)	10 (15.9%)	2 (5.7%)	12 (12.2%)
95% Exact CI	0.0788, 0.2726	0.0070, 0.1916	0.0649, 0.2041
Proportion Difference - Stratified CMH Method (95% CI)	0.12 (-0.03, 0.27)		
p-value	0.13		
Proportion Difference - Unstratified CMH Method (95% CI)	0.10 (-0.02, 0.23)		
p-value	0.11		
Proportion Difference - Unstratified Exact Method (95% CI)	0.10 (-0.11, 0.30)		
p-value	0.20		
Unadjusted Inverse Relative Risk (95% CI)	0.36 (0.08, 1.55)		
p-value [1]	0.17		
Unadjusted Inverse Odds Ratio (95% CI)	0.32 (0.07, 1.56)		
p-value [1]	0.16		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.02, 0.22)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.32 (0.07, 1.39)		
p-value [2]	0.13		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

GSK Oncology
Study GS-US-352-1214

Table 2.1418: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Inactivity) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	53 (84.1%)	33 (94.3%)	86 (87.8%)
Last participation date < Day 134 in RT Phase	15 (23.8%)	7 (20.0%)	22 (22.4%)
Last participation date >= Day 134 and Inactivity Score at Week 20 not available	1 (1.6%)	0	1 (1.0%)
>0% increase from baseline at Week 20	23 (36.5%)	16 (45.7%)	39 (39.8%)
<50% reduction from baseline at Week 20	37 (58.7%)	26 (74.3%)	63 (64.3%)
Return Rate (%)	76%	82%	78%
Number of Subjects in Risk	51	32	83
Return Rate in Risk (%)	98%	100%	99%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

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Table 2.1418: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Inactivity) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Inactivity Symptom Score at Week 24			
Subjects Evaluable at Week 24, n	63	36	99
Inactivity Score = 0 at baseline and Inactivity Score >0 or missing at Week 24	0	1 (2.8%)	1 (1.0%)
Responder, n(%)	10 (15.9%)	2 (5.6%)	12 (12.1%)
95% Exact CI	0.0788, 0.2726	0.0068, 0.1866	0.0642, 0.2022
Proportion Difference - Stratified CMH Method (95% CI)	0.11 (-0.03, 0.25)		
p-value	0.12		
Proportion Difference - Unstratified CMH Method (95% CI)	0.10 (-0.02, 0.23)		
p-value	0.10		
Proportion Difference - Unstratified Exact Method (95% CI)	0.10 (-0.10, 0.30)		
p-value	0.20		
Unadjusted Inverse Relative Risk (95% CI)	0.35 (0.08, 1.51)		
p-value [1]	0.16		
Unadjusted Inverse Odds Ratio (95% CI)	0.31 (0.06, 1.51)		
p-value [1]	0.15		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.01, 0.22)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.33 (0.08, 1.33)		
p-value [2]	0.12		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

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Table 2.1418: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Inactivity) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	53 (84.1%)	34 (94.4%)	87 (87.9%)
Last participation date < Day 162 in RT Phase	18 (28.6%)	7 (19.4%)	25 (25.3%)
Last participation date >= Day 162 and Inactivity Score at Week 24 not available	1 (1.6%)	3 (8.3%)	4 (4.0%)
>0% increase from baseline at Week 24	24 (38.1%)	15 (41.7%)	39 (39.4%)
<50% reduction from baseline at Week 24	34 (54.0%)	24 (66.7%)	58 (58.6%)
Return Rate (%)	71%	74%	72%
Number of Subjects in Risk	48	32	80
Return Rate in Risk (%)	98%	91%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

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Table 2.1417: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Pain L Ribs) by Every 4 Weeks

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Pain L Ribs Symptom Score Status			
Missing Pain L Ribs Score at baseline (excluded from rate calculation)	0	0	0
Pain L Ribs Score = 0 at baseline	22 (33.3%)	10 (25.6%)	32 (30.5%)
Pain L Ribs Score > 0 at baseline	44 (66.7%)	29 (74.4%)	73 (69.5%)
Response Rate of Pain L Ribs Symptom Score at Week 4			
Subjects Evaluable at Week 4, n	53	33	86
Pain L Ribs Score = 0 at baseline and Pain L Ribs Score >0 or missing at Week 4	9 (17.0%)	4 (12.1%)	13 (15.1%)
Responder, n(%)	9 (17.0%)	5 (15.2%)	14 (16.3%)
95% Exact CI	0.0807, 0.2980	0.0511, 0.3190	0.0920, 0.2580
Proportion Difference - Stratified CMH Method (95% CI)	0.02 (-0.15, 0.19)		
p-value	0.84		
Proportion Difference - Unstratified CMH Method (95% CI)	0.02 (-0.15, 0.18)		
p-value	0.83		
Proportion Difference - Unstratified Exact Method (95% CI)	0.02 (-0.20, 0.23)		
p-value	1.00		
Unadjusted Inverse Relative Risk (95% CI)	0.89 (0.33, 2.43)		
p-value [1]	0.82		
Unadjusted Inverse Odds Ratio (95% CI)	0.87 (0.27, 2.87)		
p-value [1]	0.82		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.14, 0.18)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.90 (0.35, 2.30)		
p-value [2]	0.82		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.1417: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Pain L Ribs) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	44 (83.0%)	28 (84.8%)	72 (83.7%)
Last participation date < Day 21 in RT Phase	0	2 (6.1%)	2 (2.3%)
Last participation date >= Day 21 and Pain L Ribs Score at Week 4 not available	0	0	0
>0% increase from baseline at Week 4	14 (26.4%)	15 (45.5%)	29 (33.7%)
<50% reduction from baseline at Week 4	35 (66.0%)	22 (66.7%)	57 (66.3%)
Return Rate (%)	100%	95%	98%
Number of Subjects in Risk	66	37	103
Return Rate in Risk (%)	100%	100%	100%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

GSK Oncology

Study GS-US-352-1214

Table 2.1417: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Pain L Ribs) by Every 4 Weeks

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Pain L Ribs Symptom Score at Week 8			
Subjects Evaluable at Week 8, n	51	34	85
Pain L Ribs Score = 0 at baseline and Pain L Ribs Score >0 or missing at Week 8	7 (13.7%)	5 (14.7%)	12 (14.1%)
Responder, n(%)	16 (31.4%)	7 (20.6%)	23 (27.1%)
95% Exact CI	0.1911, 0.4589	0.0870, 0.3790	0.1799, 0.3779
Proportion Difference - Stratified CMH Method (95% CI)	0.10 (-0.10, 0.30)		
p-value	0.33		
Proportion Difference - Unstratified CMH Method (95% CI)	0.11 (-0.08, 0.30)		
p-value	0.27		
Proportion Difference - Unstratified Exact Method (95% CI)	0.11 (-0.11, 0.32)		
p-value	0.33		
Unadjusted Inverse Relative Risk (95% CI)	0.66 (0.30, 1.42)		
p-value [1]	0.29		
Unadjusted Inverse Odds Ratio (95% CI)	0.57 (0.20, 1.57)		
p-value [1]	0.28		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.08, 0.29)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.68 (0.32, 1.46)		
p-value [2]	0.32		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

Table 2.1417: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Pain L Ribs) by Every 4 Weeks Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	35 (68.6%)	27 (79.4%)	62 (72.9%)
Last participation date < Day 50 in RT Phase	5 (9.8%)	3 (8.8%)	8 (9.4%)
Last participation date >= Day 50 and Pain L Ribs Score at Week 8 not available	2 (3.9%)	1 (2.9%)	3 (3.5%)
>0% increase from baseline at Week 8	8 (15.7%)	15 (44.1%)	23 (27.1%)
<50% reduction from baseline at Week 8	22 (43.1%)	19 (55.9%)	41 (48.2%)
Return Rate (%)	89%	90%	90%
Number of Subjects in Risk	61	36	97
Return Rate in Risk (%)	97%	97%	97%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

GSK Oncology

Study GS-US-352-1214

Table 2.1417: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Pain L Ribs) by Every 4 Weeks

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Pain L Ribs Symptom Score at Week 12			
Subjects Evaluable at Week 12, n	53	33	86
Pain L Ribs Score = 0 at baseline and Pain L Ribs Score >0 or missing at Week 12	9 (17.0%)	4 (12.1%)	13 (15.1%)
Responder, n(%)	19 (35.8%)	5 (15.2%)	24 (27.9%)
95% Exact CI	0.2314, 0.5020	0.0511, 0.3190	0.1877, 0.3862
Proportion Difference - Stratified CMH Method (95% CI)		0.19 (-0.01, 0.39)	
p-value		0.062	
Proportion Difference - Unstratified CMH Method (95% CI)		0.21 (0.02, 0.39)	
p-value		0.026	
Proportion Difference - Unstratified Exact Method (95% CI)		0.21 (-0.01, 0.41)	
p-value		0.049	
Unadjusted Inverse Relative Risk (95% CI)		0.42 (0.17, 1.02)	
p-value [1]		0.056	
Unadjusted Inverse Odds Ratio (95% CI)		0.32 (0.11, 0.96)	
p-value [1]		0.043	
Unadjusted Absolute Risk Difference (95% CI)		0.21 (0.03, 0.38)	
Adjusted Inverse Relative Risk (95% CI) [2]		0.45 (0.18, 1.11)	
p-value [2]		0.082	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.1417: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Pain L Ribs) by Every 4 Weeks

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	34 (64.2%)	28 (84.8%)	62 (72.1%)
Last participation date < Day 78 in RT Phase	7 (13.2%)	6 (18.2%)	13 (15.1%)
Last participation date >= Day 78 and Pain L Ribs Score at Week 12 not available	2 (3.8%)	0	2 (2.3%)
>0% increase from baseline at Week 12	12 (22.6%)	13 (39.4%)	25 (29.1%)
<50% reduction from baseline at Week 12	19 (35.8%)	19 (57.6%)	38 (44.2%)
Return Rate (%)	86%	85%	86%
Number of Subjects in Risk	59	33	92
Return Rate in Risk (%)	97%	100%	98%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.1417: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Pain L Ribs) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Pain L Ribs Symptom Score at Week 16			
Subjects Evaluable at Week 16, n	56	34	90
Pain L Ribs Score = 0 at baseline and Pain L Ribs Score >0 or missing at Week 16	12 (21.4%)	5 (14.7%)	17 (18.9%)
Responder, n(%)	19 (33.9%)	5 (14.7%)	24 (26.7%)
95% Exact CI	0.2181, 0.4781	0.0495, 0.3106	0.1789, 0.3703
Proportion Difference - Stratified CMH Method (95% CI)		0.20 (0.01, 0.39)	
p-value		0.041	
Proportion Difference - Unstratified CMH Method (95% CI)		0.19 (0.02, 0.37)	
p-value		0.033	
Proportion Difference - Unstratified Exact Method (95% CI)		0.19 (-0.02, 0.39)	
p-value		0.053	
Unadjusted Inverse Relative Risk (95% CI)		0.43 (0.18, 1.05)	
p-value [1]		0.065	
Unadjusted Inverse Odds Ratio (95% CI)		0.34 (0.11, 1.01)	
p-value [1]		0.052	
Unadjusted Absolute Risk Difference (95% CI)		0.19 (0.02, 0.36)	
Adjusted Inverse Relative Risk (95% CI) [2]		0.42 (0.18, 1.01)	
p-value [2]		0.053	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.1417: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Pain L Ribs) by Every 4 Weeks Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	37 (66.1%)	29 (85.3%)	66 (73.3%)
Last participation date < Day 106 in RT Phase	10 (17.9%)	7 (20.6%)	17 (18.9%)
Last participation date >= Day 106 and Pain L Ribs Score at Week 16 not available	4 (7.1%)	0	4 (4.4%)
>0% increase from baseline at Week 16	10 (17.9%)	13 (38.2%)	23 (25.6%)
<50% reduction from baseline at Week 16	17 (30.4%)	18 (52.9%)	35 (38.9%)
Return Rate (%)	79%	82%	80%
Number of Subjects in Risk	56	32	88
Return Rate in Risk (%)	93%	100%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.1417: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Pain L Ribs) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Pain L Ribs Symptom Score at Week 20			
Subjects Evaluable at Week 20, n	54	35	89
Pain L Ribs Score = 0 at baseline and Pain L Ribs Score >0 or missing at Week 20	10 (18.5%)	6 (17.1%)	16 (18.0%)
Responder, n(%)	19 (35.2%)	7 (20.0%)	26 (29.2%)
95% Exact CI	0.2268, 0.4938	0.0844, 0.3694	0.2005, 0.3981
Proportion Difference - Stratified CMH Method (95% CI)	0.16 (-0.04, 0.36)		
p-value	0.12		
Proportion Difference - Unstratified CMH Method (95% CI)	0.15 (-0.04, 0.34)		
p-value	0.11		
Proportion Difference - Unstratified Exact Method (95% CI)	0.15 (-0.06, 0.35)		
p-value	0.16		
Unadjusted Inverse Relative Risk (95% CI)	0.57 (0.27, 1.21)		
p-value [1]	0.14		
Unadjusted Inverse Odds Ratio (95% CI)	0.46 (0.17, 1.25)		
p-value [1]	0.13		
Unadjusted Absolute Risk Difference (95% CI)	0.15 (-0.03, 0.34)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.55 (0.26, 1.17)		
p-value [2]	0.12		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

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Table 2.1417: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Pain L Ribs) by Every 4 Weeks

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	35 (64.8%)	28 (80.0%)	63 (70.8%)
Last participation date < Day 134 in RT Phase	15 (27.8%)	7 (20.0%)	22 (24.7%)
Last participation date >= Day 134 and Pain L Ribs Score at Week 20 not available	1 (1.9%)	0	1 (1.1%)
>0% increase from baseline at Week 20	8 (14.8%)	12 (34.3%)	20 (22.5%)
<50% reduction from baseline at Week 20	15 (27.8%)	16 (45.7%)	31 (34.8%)
Return Rate (%)	76%	82%	78%
Number of Subjects in Risk	51	32	83
Return Rate in Risk (%)	98%	100%	99%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.1417: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Pain L Ribs) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Pain L Ribs Symptom Score at Week 24			
Subjects Evaluable at Week 24, n	54	34	88
Pain L Ribs Score = 0 at baseline and Pain L Ribs Score >0 or missing at Week 24	10 (18.5%)	5 (14.7%)	15 (17.0%)
Responder, n(%)	18 (33.3%)	4 (11.8%)	22 (25.0%)
95% Exact CI	0.2109, 0.4747	0.0330, 0.2745	0.1638, 0.3537
Proportion Difference - Stratified CMH Method (95% CI)	0.22 (0.04, 0.39)		
p-value	0.018		
Proportion Difference - Unstratified CMH Method (95% CI)	0.22 (0.04, 0.39)		
p-value	0.013		
Proportion Difference - Unstratified Exact Method (95% CI)	0.22 (0.00, 0.42)		
p-value	0.025		
Unadjusted Inverse Relative Risk (95% CI)	0.35 (0.13, 0.95)		
p-value [1]	0.040		
Unadjusted Inverse Odds Ratio (95% CI)	0.27 (0.08, 0.87)		
p-value [1]	0.029		
Unadjusted Absolute Risk Difference (95% CI)	0.22 (0.05, 0.38)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.35 (0.13, 0.93)		
p-value [2]	0.034		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

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Table 2.1417: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Pain L Ribs) by Every 4 Weeks

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	36 (66.7%)	30 (88.2%)	66 (75.0%)
Last participation date < Day 162 in RT Phase	18 (33.3%)	7 (20.6%)	25 (28.4%)
Last participation date >= Day 162 and Pain L Ribs Score at Week 24 not available	1 (1.9%)	3 (8.8%)	4 (4.5%)
>0% increase from baseline at Week 24	9 (16.7%)	13 (38.2%)	22 (25.0%)
<50% reduction from baseline at Week 24	15 (27.8%)	17 (50.0%)	32 (36.4%)
Return Rate (%)	71%	74%	72%
Number of Subjects in Risk	48	32	80
Return Rate in Risk (%)	98%	91%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.1416: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Bone Pain) by Every 4 Weeks

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Bone Pain Symptom Score Status			
Missing Bone Pain Score at baseline (excluded from rate calculation)	0	0	0
Bone Pain Score = 0 at baseline	19 (28.8%)	10 (25.6%)	29 (27.6%)
Bone Pain Score > 0 at baseline	47 (71.2%)	29 (74.4%)	76 (72.4%)
Response Rate of Bone Pain Symptom Score at Week 4			
Subjects Evaluable at Week 4, n	52	30	82
Bone Pain Score = 0 at baseline and Bone Pain Score >0 or missing at Week 4	5 (9.6%)	1 (3.3%)	6 (7.3%)
Responder, n(%)	5 (9.6%)	3 (10.0%)	8 (9.8%)
95% Exact CI	0.0320, 0.2103	0.0211, 0.2653	0.0431, 0.1832
Proportion Difference - Stratified CMH Method (95% CI)		0.00 (-0.16, 0.16)	
p-value	0.98		
Proportion Difference - Unstratified CMH Method (95% CI)		0.00 (-0.15, 0.14)	
p-value	0.96		
Proportion Difference - Unstratified Exact Method (95% CI)		0.00 (-0.22, 0.22)	
p-value	1.00		
Unadjusted Inverse Relative Risk (95% CI)		1.04 (0.27, 4.05)	
p-value [1]	0.95		
Unadjusted Inverse Odds Ratio (95% CI)		1.04 (0.23, 4.72)	
p-value [1]	0.95		
Unadjusted Absolute Risk Difference (95% CI)		0.00 (-0.14, 0.13)	
Adjusted Inverse Relative Risk (95% CI) [2]		0.98 (0.25, 3.74)	
p-value [2]	0.97		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.1416: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Bone Pain) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	47 (90.4%)	27 (90.0%)	74 (90.2%)
Last participation date < Day 21 in RT Phase	0	2 (6.7%)	2 (2.4%)
Last participation date >= Day 21 and Bone Pain Score at Week 4 not available	0	0	0
>0% increase from baseline at Week 4	19 (36.5%)	15 (50.0%)	34 (41.5%)
<50% reduction from baseline at Week 4	42 (80.8%)	24 (80.0%)	66 (80.5%)
Return Rate (%)	100%	95%	98%
Number of Subjects in Risk	66	37	103
Return Rate in Risk (%)	100%	100%	100%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

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Table 2.1416: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Bone Pain) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Bone Pain Symptom Score at Week 8			
Subjects Evaluable at Week 8, n	50	31	81
Bone Pain Score = 0 at baseline and Bone Pain Score >0 or missing at Week 8	3 (6.0%)	2 (6.5%)	5 (6.2%)
Responder, n(%)	10 (20.0%)	5 (16.1%)	15 (18.5%)
95% Exact CI	0.1003, 0.3372	0.0545, 0.3373	0.1075, 0.2870
Proportion Difference - Stratified CMH Method (95% CI)		0.05 (-0.14, 0.24)	
p-value	0.63		
Proportion Difference - Unstratified CMH Method (95% CI)		0.04 (-0.14, 0.21)	
p-value	0.67		
Proportion Difference - Unstratified Exact Method (95% CI)		0.04 (-0.18, 0.26)	
p-value	0.77		
Unadjusted Inverse Relative Risk (95% CI)		0.81 (0.30, 2.14)	
p-value [1]	0.67		
Unadjusted Inverse Odds Ratio (95% CI)		0.77 (0.24, 2.51)	
p-value [1]	0.66		
Unadjusted Absolute Risk Difference (95% CI)		0.04 (-0.13, 0.21)	
Adjusted Inverse Relative Risk (95% CI) [2]		NE	
p-value [2]	NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

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Study GS-US-352-1214

Table 2.1416: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Bone Pain) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	40 (80.0%)	26 (83.9%)	66 (81.5%)
Last participation date < Day 50 in RT Phase	5 (10.0%)	3 (9.7%)	8 (9.9%)
Last participation date >= Day 50 and Bone Pain Score at Week 8 not available	2 (4.0%)	1 (3.2%)	3 (3.7%)
>0% increase from baseline at Week 8	17 (34.0%)	14 (45.2%)	31 (38.3%)
<50% reduction from baseline at Week 8	31 (62.0%)	20 (64.5%)	51 (63.0%)
Return Rate (%)	89%	90%	90%
Number of Subjects in Risk	61	36	97
Return Rate in Risk (%)	97%	97%	97%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

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Study GS-US-352-1214

Table 2.1416: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Bone Pain) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Bone Pain Symptom Score at Week 12			
Subjects Evaluable at Week 12, n	51	29	80
Bone Pain Score = 0 at baseline and Bone Pain Score >0 or missing at Week 12	4 (7.8%)	0	4 (5.0%)
Responder, n(%)	11 (21.6%)	6 (20.7%)	17 (21.3%)
95% Exact CI	0.1129, 0.3532	0.0799, 0.3972	0.1289, 0.3183
Proportion Difference - Stratified CMH Method (95% CI)	0.02 (-0.19, 0.22)		
p-value	0.88		
Proportion Difference - Unstratified CMH Method (95% CI)	0.01 (-0.18, 0.20)		
p-value	0.93		
Proportion Difference - Unstratified Exact Method (95% CI)	0.01 (-0.22, 0.23)		
p-value	1.00		
Unadjusted Inverse Relative Risk (95% CI)	0.96 (0.40, 2.32)		
p-value [1]	0.93		
Unadjusted Inverse Odds Ratio (95% CI)	0.95 (0.31, 2.90)		
p-value [1]	0.93		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.18, 0.19)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.92 (0.38, 2.27)		
p-value [2]	0.86		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

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Table 2.1416: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Bone Pain) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	40 (78.4%)	23 (79.3%)	63 (78.8%)
Last participation date < Day 78 in RT Phase	7 (13.7%)	6 (20.7%)	13 (16.3%)
Last participation date >= Day 78 and Bone Pain Score at Week 12 not available	2 (3.9%)	0	2 (2.5%)
>0% increase from baseline at Week 12	15 (29.4%)	13 (44.8%)	28 (35.0%)
<50% reduction from baseline at Week 12	28 (54.9%)	17 (58.6%)	45 (56.3%)
Return Rate (%)	86%	85%	86%
Number of Subjects in Risk	59	33	92
Return Rate in Risk (%)	97%	100%	98%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

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Table 2.1416: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Bone Pain) by Every 4 Weeks Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Bone Pain Symptom Score at Week 16			
Subjects Evaluable at Week 16, n	56	29	85
Bone Pain Score = 0 at baseline and Bone Pain Score >0 or missing at Week 16	9 (16.1%)	0	9 (10.6%)
Responder, n(%)	11 (19.6%)	5 (17.2%)	16 (18.8%)
95% Exact CI	0.1023, 0.3243	0.0585, 0.3577	0.1116, 0.2876
Proportion Difference - Stratified CMH Method (95% CI)	0.03 (-0.17, 0.23)		
p-value	0.77		
Proportion Difference - Unstratified CMH Method (95% CI)	0.02 (-0.15, 0.20)		
p-value	0.79		
Proportion Difference - Unstratified Exact Method (95% CI)	0.02 (-0.20, 0.25)		
p-value	1.00		
Unadjusted Inverse Relative Risk (95% CI)	0.88 (0.34, 2.29)		
p-value [1]	0.79		
Unadjusted Inverse Odds Ratio (95% CI)	0.85 (0.27, 2.74)		
p-value [1]	0.79		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.15, 0.20)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.85 (0.32, 2.27)		
p-value [2]	0.75		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.1416: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Bone Pain) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	45 (80.4%)	24 (82.8%)	69 (81.2%)
Last participation date < Day 106 in RT Phase	10 (17.9%)	7 (24.1%)	17 (20.0%)
Last participation date >= Day 106 and Bone Pain Score at Week 16 not available	4 (7.1%)	0	4 (4.7%)
>0% increase from baseline at Week 16	13 (23.2%)	11 (37.9%)	24 (28.2%)
<50% reduction from baseline at Week 16	25 (44.6%)	17 (58.6%)	42 (49.4%)
Return Rate (%)	79%	82%	80%
Number of Subjects in Risk	56	32	88
Return Rate in Risk (%)	93%	100%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

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Table 2.1416: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Bone Pain) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Bone Pain Symptom Score at Week 20			
Subjects Evaluable at Week 20, n	54	30	84
Bone Pain Score = 0 at baseline and Bone Pain Score >0 or missing at Week 20	7 (13.0%)	1 (3.3%)	8 (9.5%)
Responder, n(%)	8 (14.8%)	5 (16.7%)	13 (15.5%)
95% Exact CI	0.0662, 0.2712	0.0564, 0.3472	0.0851, 0.2501
Proportion Difference - Stratified CMH Method (95% CI)	-0.02 (-0.21, 0.17)		
p-value	0.85		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.02 (-0.19, 0.15)		
p-value	0.83		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.02 (-0.24, 0.20)		
p-value	1.00		
Unadjusted Inverse Relative Risk (95% CI)	1.13 (0.40, 3.13)		
p-value [1]	0.82		
Unadjusted Inverse Odds Ratio (95% CI)	1.15 (0.34, 3.89)		
p-value [1]	0.82		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.18, 0.15)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.13 (0.41, 3.11)		
p-value [2]	0.82		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

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Table 2.1416: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Bone Pain) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	46 (85.2%)	25 (83.3%)	71 (84.5%)
Last participation date < Day 134 in RT Phase	15 (27.8%)	7 (23.3%)	22 (26.2%)
Last participation date >= Day 134 and Bone Pain Score at Week 20 not available	1 (1.9%)	0	1 (1.2%)
>0% increase from baseline at Week 20	14 (25.9%)	12 (40.0%)	26 (31.0%)
<50% reduction from baseline at Week 20	26 (48.1%)	17 (56.7%)	43 (51.2%)
Return Rate (%)	76%	82%	78%
Number of Subjects in Risk	51	32	83
Return Rate in Risk (%)	98%	100%	99%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

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Table 2.1416: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Bone Pain) by Every 4 Weeks Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Bone Pain Symptom Score at Week 24			
Subjects Evaluable at Week 24, n	54	31	85
Bone Pain Score = 0 at baseline and Bone Pain Score >0 or missing at Week 24	7 (13.0%)	2 (6.5%)	9 (10.6%)
Responder, n(%)	10 (18.5%)	4 (12.9%)	14 (16.5%)
95% Exact CI	0.0925, 0.3143	0.0363, 0.2983	0.0931, 0.2609
Proportion Difference - Stratified CMH Method (95% CI)	0.07 (-0.11, 0.25)		
p-value	0.45		
Proportion Difference - Unstratified CMH Method (95% CI)	0.06 (-0.11, 0.22)		
p-value	0.50		
Proportion Difference - Unstratified Exact Method (95% CI)	0.06 (-0.16, 0.27)		
p-value	0.56		
Unadjusted Inverse Relative Risk (95% CI)	0.70 (0.24, 2.04)		
p-value [1]	0.51		
Unadjusted Inverse Odds Ratio (95% CI)	0.65 (0.19, 2.29)		
p-value [1]	0.50		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.10, 0.21)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.64 (0.22, 1.84)		
p-value [2]	0.40		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

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Table 2.1416: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Bone Pain) by Every 4 Weeks Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	44 (81.5%)	27 (87.1%)	71 (83.5%)
Last participation date < Day 162 in RT Phase	18 (33.3%)	7 (22.6%)	25 (29.4%)
Last participation date >= Day 162 and Bone Pain Score at Week 24 not available	1 (1.9%)	3 (9.7%)	4 (4.7%)
>0% increase from baseline at Week 24	10 (18.5%)	13 (41.9%)	23 (27.1%)
<50% reduction from baseline at Week 24	22 (40.7%)	16 (51.6%)	38 (44.7%)
Return Rate (%)	71%	74%	72%
Number of Subjects in Risk	48	32	80
Return Rate in Risk (%)	98%	91%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

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Table 2.1415: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Itching) by Every 4 Weeks

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Itching Symptom Score Status			
Missing Itching Score at baseline (excluded from rate calculation)	0	0	0
Itching Score = 0 at baseline	31 (47.0%)	15 (38.5%)	46 (43.8%)
Itching Score > 0 at baseline	35 (53.0%)	24 (61.5%)	59 (56.2%)
Response Rate of Itching Symptom Score at Week 4			
Subjects Evaluable at Week 4, n	47	27	74
Itching Score = 0 at baseline and Itching Score >0 or missing at Week 4	12 (25.5%)	3 (11.1%)	15 (20.3%)
Responder, n(%)	5 (10.6%)	5 (18.5%)	10 (13.5%)
95% Exact CI	0.0355, 0.2310	0.0630, 0.3808	0.0668, 0.2345
Proportion Difference - Stratified CMH Method (95% CI)		-0.09 (-0.28, 0.10)	
p-value	0.34		
Proportion Difference - Unstratified CMH Method (95% CI)		-0.08 (-0.26, 0.10)	
p-value	0.39		
Proportion Difference - Unstratified Exact Method (95% CI)		-0.08 (-0.31, 0.16)	
p-value	0.48		
Unadjusted Inverse Relative Risk (95% CI)		1.74 (0.55, 5.47)	
p-value [1]	0.34		
Unadjusted Inverse Odds Ratio (95% CI)		1.91 (0.50, 7.31)	
p-value [1]	0.35		
Unadjusted Absolute Risk Difference (95% CI)		-0.08 (-0.25, 0.09)	
Adjusted Inverse Relative Risk (95% CI) [2]		1.90 (0.68, 5.33)	
p-value [2]	0.22		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.1415: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Itching) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	42 (89.4%)	22 (81.5%)	64 (86.5%)
Last participation date < Day 21 in RT Phase	0	2 (7.4%)	2 (2.7%)
Last participation date >= Day 21 and Itching Score at Week 4 not available	0	0	0
>0% increase from baseline at Week 4	13 (27.7%)	13 (48.1%)	26 (35.1%)
<50% reduction from baseline at Week 4	30 (63.8%)	18 (66.7%)	48 (64.9%)
Return Rate (%)	100%	95%	98%
Number of Subjects in Risk	66	37	103
Return Rate in Risk (%)	100%	100%	100%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

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Table 2.1415: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Itching) by Every 4 Weeks

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Itching Symptom Score at Week 8			
Subjects Evaluable at Week 8, n	47	30	77
Itching Score = 0 at baseline and Itching Score >0 or missing at Week 8	12 (25.5%)	6 (20.0%)	18 (23.4%)
Responder, n(%)	13 (27.7%)	7 (23.3%)	20 (26.0%)
95% Exact CI	0.1562, 0.4264	0.0993, 0.4228	0.1664, 0.3723
Proportion Difference - Stratified CMH Method (95% CI)		0.03 (-0.19, 0.24)	
p-value	0.80		
Proportion Difference - Unstratified CMH Method (95% CI)		0.04 (-0.16, 0.25)	
p-value	0.68		
Proportion Difference - Unstratified Exact Method (95% CI)		0.04 (-0.19, 0.27)	
p-value	0.79		
Unadjusted Inverse Relative Risk (95% CI)		0.84 (0.38, 1.87)	
p-value [1]	0.68		
Unadjusted Inverse Odds Ratio (95% CI)		0.80 (0.28, 2.30)	
p-value [1]	0.67		
Unadjusted Absolute Risk Difference (95% CI)		0.04 (-0.15, 0.24)	
Adjusted Inverse Relative Risk (95% CI) [2]		NE	
p-value [2]	NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

GSK Oncology
Study GS-US-352-1214

Table 2.1415: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Itching) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	34 (72.3%)	23 (76.7%)	57 (74.0%)
Last participation date < Day 50 in RT Phase	5 (10.6%)	3 (10.0%)	8 (10.4%)
Last participation date >= Day 50 and Itching Score at Week 8 not available	2 (4.3%)	1 (3.3%)	3 (3.9%)
>0% increase from baseline at Week 8	12 (25.5%)	12 (40.0%)	24 (31.2%)
<50% reduction from baseline at Week 8	18 (38.3%)	16 (53.3%)	34 (44.2%)
Return Rate (%)	89%	90%	90%
Number of Subjects in Risk	61	36	97
Return Rate in Risk (%)	97%	97%	97%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

GSK Oncology
Study GS-US-352-1214

Table 2.1415: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Itching) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Itching Symptom Score at Week 12			
Subjects Evaluable at Week 12, n	48	30	78
Itching Score = 0 at baseline and Itching Score >0 or missing at Week 12	13 (27.1%)	6 (20.0%)	19 (24.4%)
Responder, n(%)	13 (27.1%)	5 (16.7%)	18 (23.1%)
95% Exact CI	0.1528, 0.4185	0.0564, 0.3472	0.1429, 0.3400
Proportion Difference - Stratified CMH Method (95% CI)	0.08 (-0.12, 0.29)		
p-value	0.43		
Proportion Difference - Unstratified CMH Method (95% CI)	0.10 (-0.08, 0.29)		
p-value	0.28		
Proportion Difference - Unstratified Exact Method (95% CI)	0.10 (-0.13, 0.33)		
p-value	0.41		
Unadjusted Inverse Relative Risk (95% CI)	0.62 (0.24, 1.55)		
p-value [1]	0.30		
Unadjusted Inverse Odds Ratio (95% CI)	0.54 (0.17, 1.70)		
p-value [1]	0.29		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.08, 0.29)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

GSK Oncology
Study GS-US-352-1214

Table 2.1415: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Itching) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	35 (72.9%)	25 (83.3%)	60 (76.9%)
Last participation date < Day 78 in RT Phase	6 (12.5%)	6 (20.0%)	12 (15.4%)
Last participation date >= Day 78 and Itching Score at Week 12 not available	2 (4.2%)	0	2 (2.6%)
>0% increase from baseline at Week 12	12 (25.0%)	13 (43.3%)	25 (32.1%)
<50% reduction from baseline at Week 12	19 (39.6%)	17 (56.7%)	36 (46.2%)
Return Rate (%)	88%	85%	87%
Number of Subjects in Risk	60	33	93
Return Rate in Risk (%)	97%	100%	98%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

GSK Oncology
Study GS-US-352-1214

Table 2.1415: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Itching) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Itching Symptom Score at Week 16			
Subjects Evaluable at Week 16, n	46	31	77
Itching Score = 0 at baseline and Itching Score >0 or missing at Week 16	11 (23.9%)	7 (22.6%)	18 (23.4%)
Responder, n(%)	11 (23.9%)	5 (16.1%)	16 (20.8%)
95% Exact CI	0.1259, 0.3877	0.0545, 0.3373	0.1237, 0.3154
Proportion Difference - Stratified CMH Method (95% CI)	0.06 (-0.15, 0.26)		
p-value	0.59		
Proportion Difference - Unstratified CMH Method (95% CI)	0.08 (-0.11, 0.26)		
p-value	0.41		
Proportion Difference - Unstratified Exact Method (95% CI)	0.08 (-0.15, 0.30)		
p-value	0.57		
Unadjusted Inverse Relative Risk (95% CI)	0.67 (0.26, 1.75)		
p-value [1]	0.42		
Unadjusted Inverse Odds Ratio (95% CI)	0.61 (0.19, 1.98)		
p-value [1]	0.41		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.10, 0.26)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

GSK Oncology
Study GS-US-352-1214

Table 2.1415: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Itching) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	35 (76.1%)	26 (83.9%)	61 (79.2%)
Last participation date < Day 106 in RT Phase	10 (21.7%)	7 (22.6%)	17 (22.1%)
Last participation date >= Day 106 and Itching Score at Week 16 not available	4 (8.7%)	0	4 (5.2%)
>0% increase from baseline at Week 16	7 (15.2%)	13 (41.9%)	20 (26.0%)
<50% reduction from baseline at Week 16	16 (34.8%)	16 (51.6%)	32 (41.6%)
Return Rate (%)	79%	82%	80%
Number of Subjects in Risk	56	32	88
Return Rate in Risk (%)	93%	100%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

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Table 2.1415: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Itching) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Itching Symptom Score at Week 20			
Subjects Evaluable at Week 20, n	48	31	79
Itching Score = 0 at baseline and Itching Score >0 or missing at Week 20	13 (27.1%)	7 (22.6%)	20 (25.3%)
Responder, n(%)	16 (33.3%)	5 (16.1%)	21 (26.6%)
95% Exact CI	0.2040, 0.4841	0.0545, 0.3373	0.1727, 0.3772
Proportion Difference - Stratified CMH Method (95% CI)	0.15 (-0.06, 0.35)		
p-value	0.17		
Proportion Difference - Unstratified CMH Method (95% CI)	0.17 (-0.02, 0.36)		
p-value	0.077		
Proportion Difference - Unstratified Exact Method (95% CI)	0.17 (-0.06, 0.39)		
p-value	0.12		
Unadjusted Inverse Relative Risk (95% CI)	0.48 (0.20, 1.19)		
p-value [1]	0.11		
Unadjusted Inverse Odds Ratio (95% CI)	0.38 (0.12, 1.19)		
p-value [1]	0.097		
Unadjusted Absolute Risk Difference (95% CI)	0.17 (-0.01, 0.36)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

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Table 2.1415: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Itching) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	32 (66.7%)	26 (83.9%)	58 (73.4%)
Last participation date < Day 134 in RT Phase	15 (31.3%)	7 (22.6%)	22 (27.8%)
Last participation date >= Day 134 and Itching Score at Week 20 not available	1 (2.1%)	0	1 (1.3%)
>0% increase from baseline at Week 20	7 (14.6%)	13 (41.9%)	20 (25.3%)
<50% reduction from baseline at Week 20	10 (20.8%)	16 (51.6%)	26 (32.9%)
Return Rate (%)	76%	82%	78%
Number of Subjects in Risk	51	32	83
Return Rate in Risk (%)	98%	100%	99%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

GSK Oncology
Study GS-US-352-1214

Table 2.1415: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Itching) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Itching Symptom Score at Week 24			
Subjects Evaluable at Week 24, n	50	33	83
Itching Score = 0 at baseline and Itching Score >0 or missing at Week 24	15 (30.0%)	9 (27.3%)	24 (28.9%)
Responder, n(%)	14 (28.0%)	3 (9.1%)	17 (20.5%)
95% Exact CI	0.1623, 0.4249	0.0192, 0.2433	0.1241, 0.3076
Proportion Difference - Stratified CMH Method (95% CI)	0.19 (0.01, 0.37)		
p-value	0.040		
Proportion Difference - Unstratified CMH Method (95% CI)	0.19 (0.02, 0.35)		
p-value	0.024		
Proportion Difference - Unstratified Exact Method (95% CI)	0.19 (-0.03, 0.40)		
p-value	0.051		
Unadjusted Inverse Relative Risk (95% CI)	0.32 (0.10, 1.04)		
p-value [1]	0.059		
Unadjusted Inverse Odds Ratio (95% CI)	0.26 (0.07, 0.98)		
p-value [1]	0.047		
Unadjusted Absolute Risk Difference (95% CI)	0.19 (0.03, 0.35)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

GSK Oncology
Study GS-US-352-1214

Table 2.1415: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Itching) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	36 (72.0%)	30 (90.9%)	66 (79.5%)
Last participation date < Day 162 in RT Phase	18 (36.0%)	7 (21.2%)	25 (30.1%)
Last participation date >= Day 162 and Itching Score at Week 24 not available	1 (2.0%)	3 (9.1%)	4 (4.8%)
>0% increase from baseline at Week 24	5 (10.0%)	13 (39.4%)	18 (21.7%)
<50% reduction from baseline at Week 24	9 (18.0%)	16 (48.5%)	25 (30.1%)
Return Rate (%)	71%	74%	72%
Number of Subjects in Risk	48	32	80
Return Rate in Risk (%)	98%	91%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

GSK Oncology

Study GS-US-352-1214

Table 2.1414: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Night Sweats) by Every 4 Weeks

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Night Sweats Symptom Score Status			
Missing Night Sweats Score at baseline (excluded from rate calculation)	0	0	0
Night Sweats Score = 0 at baseline	20 (30.3%)	15 (38.5%)	35 (33.3%)
Night Sweats Score > 0 at baseline	46 (69.7%)	24 (61.5%)	70 (66.7%)
Response Rate of Night Sweats Symptom Score at Week 4			
Subjects Evaluable at Week 4, n	51	30	81
Night Sweats Score = 0 at baseline and Night Sweats Score >0 or missing at Week 4	5 (9.8%)	6 (20.0%)	11 (13.6%)
Responder, n(%)	9 (17.6%)	3 (10.0%)	12 (14.8%)
95% Exact CI	0.0840, 0.3087	0.0211, 0.2653	0.0790, 0.2445
Proportion Difference - Stratified CMH Method (95% CI)	0.08 (-0.09, 0.26)		
p-value	0.35		
Proportion Difference - Unstratified CMH Method (95% CI)	0.08 (-0.08, 0.23)		
p-value	0.34		
Proportion Difference - Unstratified Exact Method (95% CI)	0.08 (-0.15, 0.30)		
p-value	0.52		
Unadjusted Inverse Relative Risk (95% CI)	0.57 (0.17, 1.93)		
p-value [1]	0.36		
Unadjusted Inverse Odds Ratio (95% CI)	0.52 (0.13, 2.09)		
p-value [1]	0.36		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.07, 0.23)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.54 (0.16, 1.80)		
p-value [2]	0.32		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

GSK Oncology

Study GS-US-352-1214

Table 2.1414: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Night Sweats) by Every 4 Weeks

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	42 (82.4%)	27 (90.0%)	69 (85.2%)
Last participation date < Day 21 in RT Phase	0	2 (6.7%)	2 (2.5%)
Last participation date >= Day 21 and Night Sweats Score at Week 4 not available	0	0	0
>0% increase from baseline at Week 4	16 (31.4%)	11 (36.7%)	27 (33.3%)
<50% reduction from baseline at Week 4	37 (72.5%)	19 (63.3%)	56 (69.1%)
Return Rate (%)	100%	95%	98%
Number of Subjects in Risk	66	37	103
Return Rate in Risk (%)	100%	100%	100%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.1414: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Night Sweats) by Every 4 Weeks

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Night Sweats Symptom Score at Week 8			
Subjects Evaluable at Week 8, n	53	29	82
Night Sweats Score = 0 at baseline and Night Sweats Score >0 or missing at Week 8	7 (13.2%)	5 (17.2%)	12 (14.6%)
Responder, n(%)	11 (20.8%)	7 (24.1%)	18 (22.0%)
95% Exact CI	0.1084, 0.3411	0.1030, 0.4354	0.1356, 0.3246
Proportion Difference - Stratified CMH Method (95% CI)	-0.03 (-0.24, 0.18)		
p-value	0.79		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.03 (-0.23, 0.16)		
p-value	0.73		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.03 (-0.26, 0.19)		
p-value	0.78		
Unadjusted Inverse Relative Risk (95% CI)	1.16 (0.51, 2.67)		
p-value [1]	0.72		
Unadjusted Inverse Odds Ratio (95% CI)	1.21 (0.41, 3.57)		
p-value [1]	0.72		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.22, 0.16)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.14 (0.49, 2.63)		
p-value [2]	0.77		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.1414: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Night Sweats) by Every 4 Weeks

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	42 (79.2%)	22 (75.9%)	64 (78.0%)
Last participation date < Day 50 in RT Phase	5 (9.4%)	3 (10.3%)	8 (9.8%)
Last participation date >= Day 50 and Night Sweats Score at Week 8 not available	2 (3.8%)	1 (3.4%)	3 (3.7%)
>0% increase from baseline at Week 8	10 (18.9%)	10 (34.5%)	20 (24.4%)
<50% reduction from baseline at Week 8	29 (54.7%)	14 (48.3%)	43 (52.4%)
Return Rate (%)	89%	90%	90%
Number of Subjects in Risk	61	36	97
Return Rate in Risk (%)	97%	97%	97%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

GSK Oncology
Study GS-US-352-1214

Table 2.1414: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Night Sweats) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Night Sweats Symptom Score at Week 12			
Subjects Evaluable at Week 12, n	53	28	81
Night Sweats Score = 0 at baseline and Night Sweats Score >0 or missing at Week 12	7 (13.2%)	4 (14.3%)	11 (13.6%)
Responder, n(%)	16 (30.2%)	7 (25.0%)	23 (28.4%)
95% Exact CI	0.1834, 0.4434	0.1069, 0.4487	0.1893, 0.3950
Proportion Difference - Stratified CMH Method (95% CI)	0.08 (-0.15, 0.30)		
p-value	0.51		
Proportion Difference - Unstratified CMH Method (95% CI)	0.05 (-0.16, 0.26)		
p-value	0.62		
Proportion Difference - Unstratified Exact Method (95% CI)	0.05 (-0.18, 0.28)		
p-value	0.80		
Unadjusted Inverse Relative Risk (95% CI)	0.83 (0.39, 1.77)		
p-value [1]	0.63		
Unadjusted Inverse Odds Ratio (95% CI)	0.77 (0.27, 2.17)		
p-value [1]	0.62		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.15, 0.25)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.76 (0.35, 1.67)		
p-value [2]	0.50		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

GSK Oncology

Study GS-US-352-1214

Table 2.1414: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Night Sweats) by Every 4 Weeks

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	37 (69.8%)	21 (75.0%)	58 (71.6%)
Last participation date < Day 78 in RT Phase	7 (13.2%)	6 (21.4%)	13 (16.0%)
Last participation date >= Day 78 and Night Sweats Score at Week 12 not available	2 (3.8%)	0	2 (2.5%)
>0% increase from baseline at Week 12	6 (11.3%)	7 (25.0%)	13 (16.0%)
<50% reduction from baseline at Week 12	23 (43.4%)	13 (46.4%)	36 (44.4%)
Return Rate (%)	86%	85%	86%
Number of Subjects in Risk	59	33	92
Return Rate in Risk (%)	97%	100%	98%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

GSK Oncology
Study GS-US-352-1214

Table 2.1414: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Night Sweats) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Night Sweats Symptom Score at Week 16			
Subjects Evaluable at Week 16, n	53	29	82
Night Sweats Score = 0 at baseline and Night Sweats Score >0 or missing at Week 16	7 (13.2%)	5 (17.2%)	12 (14.6%)
Responder, n(%)	15 (28.3%)	7 (24.1%)	22 (26.8%)
95% Exact CI	0.1679, 0.4235	0.1030, 0.4354	0.1764, 0.3776
Proportion Difference - Stratified CMH Method (95% CI)		0.06 (-0.15, 0.28)	
p-value	0.56		
Proportion Difference - Unstratified CMH Method (95% CI)		0.04 (-0.16, 0.24)	
p-value	0.69		
Proportion Difference - Unstratified Exact Method (95% CI)		0.04 (-0.18, 0.26)	
p-value	0.80		
Unadjusted Inverse Relative Risk (95% CI)		0.85 (0.39, 1.85)	
p-value [1]	0.69		
Unadjusted Inverse Odds Ratio (95% CI)		0.81 (0.29, 2.28)	
p-value [1]	0.68		
Unadjusted Absolute Risk Difference (95% CI)		0.04 (-0.16, 0.24)	
Adjusted Inverse Relative Risk (95% CI) [2]		0.78 (0.35, 1.72)	
p-value [2]	0.54		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

GSK Oncology

Study GS-US-352-1214

Table 2.1414: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Night Sweats) by Every 4 Weeks

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	38 (71.7%)	22 (75.9%)	60 (73.2%)
Last participation date < Day 106 in RT Phase	10 (18.9%)	7 (24.1%)	17 (20.7%)
Last participation date >= Day 106 and Night Sweats Score at Week 16 not available	4 (7.5%)	0	4 (4.9%)
>0% increase from baseline at Week 16	3 (5.7%)	6 (20.7%)	9 (11.0%)
<50% reduction from baseline at Week 16	19 (35.8%)	13 (44.8%)	32 (39.0%)
Return Rate (%)	79%	82%	80%
Number of Subjects in Risk	56	32	88
Return Rate in Risk (%)	93%	100%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

GSK Oncology

Study GS-US-352-1214

Table 2.1414: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Night Sweats) by Every 4 Weeks

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Night Sweats Symptom Score at Week 20			
Subjects Evaluable at Week 20, n	53	30	83
Night Sweats Score = 0 at baseline and Night Sweats Score >0 or missing at Week 20	7 (13.2%)	6 (20.0%)	13 (15.7%)
Responder, n(%)	19 (35.8%)	8 (26.7%)	27 (32.5%)
95% Exact CI	0.2314, 0.5020	0.1228, 0.4589	0.2265, 0.4370
Proportion Difference - Stratified CMH Method (95% CI)	0.08 (-0.13, 0.30)		
p-value	0.45		
Proportion Difference - Unstratified CMH Method (95% CI)	0.09 (-0.12, 0.30)		
p-value	0.39		
Proportion Difference - Unstratified Exact Method (95% CI)	0.09 (-0.13, 0.31)		
p-value	0.47		
Unadjusted Inverse Relative Risk (95% CI)	0.74 (0.37, 1.49)		
p-value [1]	0.40		
Unadjusted Inverse Odds Ratio (95% CI)	0.65 (0.24, 1.74)		
p-value [1]	0.39		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.11, 0.30)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.76 (0.38, 1.51)		
p-value [2]	0.43		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

GSK Oncology

Study GS-US-352-1214

Table 2.1414: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Night Sweats) by Every 4 Weeks

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	34 (64.2%)	22 (73.3%)	56 (67.5%)
Last participation date < Day 134 in RT Phase	15 (28.3%)	7 (23.3%)	22 (26.5%)
Last participation date >= Day 134 and Night Sweats Score at Week 20 not available	1 (1.9%)	0	1 (1.2%)
>0% increase from baseline at Week 20	5 (9.4%)	6 (20.0%)	11 (13.3%)
<50% reduction from baseline at Week 20	13 (24.5%)	12 (40.0%)	25 (30.1%)
Return Rate (%)	76%	82%	78%
Number of Subjects in Risk	51	32	83
Return Rate in Risk (%)	98%	100%	99%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

GSK Oncology

Study GS-US-352-1214

Table 2.1414: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Night Sweats) by Every 4 Weeks

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Night Sweats Symptom Score at Week 24			
Subjects Evaluable at Week 24, n	53	33	86
Night Sweats Score = 0 at baseline and Night Sweats Score >0 or missing at Week 24	7 (13.2%)	9 (27.3%)	16 (18.6%)
Responder, n(%)	15 (28.3%)	6 (18.2%)	21 (24.4%)
95% Exact CI	0.1679, 0.4235	0.0698, 0.3546	0.1580, 0.3487
Proportion Difference - Stratified CMH Method (95% CI)		0.11 (-0.09, 0.31)	
p-value	0.27		
Proportion Difference - Unstratified CMH Method (95% CI)		0.10 (-0.08, 0.28)	
p-value	0.28		
Proportion Difference - Unstratified Exact Method (95% CI)		0.10 (-0.12, 0.31)	
p-value	0.32		
Unadjusted Inverse Relative Risk (95% CI)		0.64 (0.28, 1.49)	
p-value [1]	0.30		
Unadjusted Inverse Odds Ratio (95% CI)		0.56 (0.19, 1.64)	
p-value [1]	0.29		
Unadjusted Absolute Risk Difference (95% CI)		0.10 (-0.08, 0.28)	
Adjusted Inverse Relative Risk (95% CI) [2]		0.61 (0.26, 1.43)	
p-value [2]	0.26		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

GSK Oncology

Study GS-US-352-1214

Table 2.1414: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Night Sweats) by Every 4 Weeks

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	38 (71.7%)	27 (81.8%)	65 (75.6%)
Last participation date < Day 162 in RT Phase	18 (34.0%)	7 (21.2%)	25 (29.1%)
Last participation date >= Day 162 and Night Sweats Score at Week 24 not available	1 (1.9%)	3 (9.1%)	4 (4.7%)
>0% increase from baseline at Week 24	4 (7.5%)	5 (15.2%)	9 (10.5%)
<50% reduction from baseline at Week 24	15 (28.3%)	12 (36.4%)	27 (31.4%)
Return Rate (%)	71%	74%	72%
Number of Subjects in Risk	48	32	80
Return Rate in Risk (%)	98%	91%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

GSK Oncology

Study GS-US-352-1214

Table 2.1413: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Ab Discomfort) by Every 4 Weeks

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Ab Discomfort Symptom Score Status			
Missing Ab Discomfort Score at baseline (excluded from rate calculation)	0	0	0
Ab Discomfort Score = 0 at baseline	10 (15.2%)	8 (20.5%)	18 (17.1%)
Ab Discomfort Score > 0 at baseline	56 (84.8%)	31 (79.5%)	87 (82.9%)
Response Rate of Ab Discomfort Symptom Score at Week 4			
Subjects Evaluable at Week 4, n	60	34	94
Ab Discomfort Score = 0 at baseline and Ab Discomfort Score >0 or missing at Week 4	4 (6.7%)	3 (8.8%)	7 (7.4%)
Responder, n(%)	10 (16.7%)	5 (14.7%)	15 (16.0%)
95% Exact CI	0.0829, 0.2852	0.0495, 0.3106	0.0922, 0.2495
Proportion Difference - Stratified CMH Method (95% CI)	0.01 (-0.16, 0.17)		
p-value	0.93		
Proportion Difference - Unstratified CMH Method (95% CI)	0.02 (-0.14, 0.18)		
p-value	0.81		
Proportion Difference - Unstratified Exact Method (95% CI)	0.02 (-0.19, 0.23)		
p-value	1.00		
Unadjusted Inverse Relative Risk (95% CI)	0.88 (0.33, 2.37)		
p-value [1]	0.80		
Unadjusted Inverse Odds Ratio (95% CI)	0.86 (0.27, 2.77)		
p-value [1]	0.80		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.13, 0.17)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.95 (0.37, 2.44)		
p-value [2]	0.92		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

GSK Oncology
Study GS-US-352-1214

Table 2.1413: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Ab Discomfort) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	50 (83.3%)	29 (85.3%)	79 (84.0%)
Last participation date < Day 21 in RT Phase	0	2 (5.9%)	2 (2.1%)
Last participation date >= Day 21 and Ab Discomfort Score at Week 4 not available	0	0	0
>0% increase from baseline at Week 4	21 (35.0%)	13 (38.2%)	34 (36.2%)
<50% reduction from baseline at Week 4	46 (76.7%)	24 (70.6%)	70 (74.5%)
Return Rate (%)	100%	95%	98%
Number of Subjects in Risk	66	37	103
Return Rate in Risk (%)	100%	100%	100%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Study GS-US-352-1214

Table 2.1413: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Ab Discomfort) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Ab Discomfort Symptom Score at Week 8			
Subjects Evaluable at Week 8, n	60	35	95
Ab Discomfort Score = 0 at baseline and Ab Discomfort Score >0 or missing at Week 8	4 (6.7%)	4 (11.4%)	8 (8.4%)
Responder, n(%)	18 (30.0%)	7 (20.0%)	25 (26.3%)
95% Exact CI	0.1885, 0.4321	0.0844, 0.3694	0.1781, 0.3635
Proportion Difference - Stratified CMH Method (95% CI)	0.08 (-0.11, 0.26)		
p-value	0.43		
Proportion Difference - Unstratified CMH Method (95% CI)	0.10 (-0.08, 0.28)		
p-value	0.28		
Proportion Difference - Unstratified Exact Method (95% CI)	0.10 (-0.11, 0.30)		
p-value	0.34		
Unadjusted Inverse Relative Risk (95% CI)	0.67 (0.31, 1.44)		
p-value [1]	0.30		
Unadjusted Inverse Odds Ratio (95% CI)	0.58 (0.22, 1.58)		
p-value [1]	0.29		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.08, 0.28)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.73 (0.34, 1.56)		
p-value [2]	0.42		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

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Table 2.1413: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Ab Discomfort) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	42 (70.0%)	28 (80.0%)	70 (73.7%)
Last participation date < Day 50 in RT Phase	5 (8.3%)	3 (8.6%)	8 (8.4%)
Last participation date >= Day 50 and Ab Discomfort Score at Week 8 not available	2 (3.3%)	1 (2.9%)	3 (3.2%)
>0% increase from baseline at Week 8	15 (25.0%)	13 (37.1%)	28 (29.5%)
<50% reduction from baseline at Week 8	31 (51.7%)	21 (60.0%)	52 (54.7%)
Return Rate (%)	89%	90%	90%
Number of Subjects in Risk	61	36	97
Return Rate in Risk (%)	97%	97%	97%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

GSK Oncology
Study GS-US-352-1214

Table 2.1413: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Ab Discomfort) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Ab Discomfort Symptom Score at Week 12			
Subjects Evaluable at Week 12, n	58	35	93
Ab Discomfort Score = 0 at baseline and Ab Discomfort Score >0 or missing at Week 12	2 (3.4%)	4 (11.4%)	6 (6.5%)
Responder, n(%)	21 (36.2%)	7 (20.0%)	28 (30.1%)
95% Exact CI	0.2399, 0.4988	0.0844, 0.3694	0.2103, 0.4050
Proportion Difference - Stratified CMH Method (95% CI)		0.15 (-0.05, 0.35)	
p-value		0.15	
Proportion Difference - Unstratified CMH Method (95% CI)		0.16 (-0.02, 0.35)	
p-value		0.086	
Proportion Difference - Unstratified Exact Method (95% CI)		0.16 (-0.05, 0.36)	
p-value		0.11	
Unadjusted Inverse Relative Risk (95% CI)		0.55 (0.26, 1.16)	
p-value [1]		0.12	
Unadjusted Inverse Odds Ratio (95% CI)		0.44 (0.16, 1.18)	
p-value [1]		0.10	
Unadjusted Absolute Risk Difference (95% CI)		0.16 (-0.02, 0.34)	
Adjusted Inverse Relative Risk (95% CI) [2]		0.58 (0.27, 1.24)	
p-value [2]		0.16	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

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Table 2.1413: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Ab Discomfort) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	37 (63.8%)	28 (80.0%)	65 (69.9%)
Last participation date < Day 78 in RT Phase	7 (12.1%)	6 (17.1%)	13 (14.0%)
Last participation date >= Day 78 and Ab Discomfort Score at Week 12 not available	2 (3.4%)	0	2 (2.2%)
>0% increase from baseline at Week 12	11 (19.0%)	12 (34.3%)	23 (24.7%)
<50% reduction from baseline at Week 12	26 (44.8%)	19 (54.3%)	45 (48.4%)
Return Rate (%)	86%	85%	86%
Number of Subjects in Risk	59	33	92
Return Rate in Risk (%)	97%	100%	98%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.1413: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Ab Discomfort) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Ab Discomfort Symptom Score at Week 16			
Subjects Evaluable at Week 16, n	60	35	95
Ab Discomfort Score = 0 at baseline and Ab Discomfort Score >0 or missing at Week 16	4 (6.7%)	4 (11.4%)	8 (8.4%)
Responder, n(%)	19 (31.7%)	5 (14.3%)	24 (25.3%)
95% Exact CI	0.2026, 0.4496	0.0481, 0.3026	0.1691, 0.3522
Proportion Difference - Stratified CMH Method (95% CI)		0.17 (-0.02, 0.35)	
p-value		0.075	
Proportion Difference - Unstratified CMH Method (95% CI)		0.17 (0.00, 0.34)	
p-value		0.045	
Proportion Difference - Unstratified Exact Method (95% CI)		0.17 (-0.04, 0.37)	
p-value		0.086	
Unadjusted Inverse Relative Risk (95% CI)		0.45 (0.18, 1.10)	
p-value [1]		0.080	
Unadjusted Inverse Odds Ratio (95% CI)		0.36 (0.12, 1.07)	
p-value [1]		0.066	
Unadjusted Absolute Risk Difference (95% CI)		0.17 (0.01, 0.34)	
Adjusted Inverse Relative Risk (95% CI) [2]		0.46 (0.19, 1.15)	
p-value [2]		0.095	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

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Table 2.1413: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Ab Discomfort) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	41 (68.3%)	30 (85.7%)	71 (74.7%)
Last participation date < Day 106 in RT Phase	10 (16.7%)	7 (20.0%)	17 (17.9%)
Last participation date >= Day 106 and Ab Discomfort Score at Week 16 not available	4 (6.7%)	0	4 (4.2%)
>0% increase from baseline at Week 16	12 (20.0%)	13 (37.1%)	25 (26.3%)
<50% reduction from baseline at Week 16	23 (38.3%)	20 (57.1%)	43 (45.3%)
Return Rate (%)	79%	82%	80%
Number of Subjects in Risk	56	32	88
Return Rate in Risk (%)	93%	100%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

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Table 2.1413: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Ab Discomfort) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Ab Discomfort Symptom Score at Week 20			
Subjects Evaluable at Week 20, n	60	35	95
Ab Discomfort Score = 0 at baseline and Ab Discomfort Score >0 or missing at Week 20	4 (6.7%)	4 (11.4%)	8 (8.4%)
Responder, n(%)	20 (33.3%)	7 (20.0%)	27 (28.4%)
95% Exact CI	0.2169, 0.4669	0.0844, 0.3694	0.1964, 0.3860
Proportion Difference - Stratified CMH Method (95% CI)	0.11 (-0.09, 0.30)		
p-value	0.27		
Proportion Difference - Unstratified CMH Method (95% CI)	0.13 (-0.05, 0.32)		
p-value	0.15		
Proportion Difference - Unstratified Exact Method (95% CI)	0.13 (-0.08, 0.33)		
p-value	0.24		
Unadjusted Inverse Relative Risk (95% CI)	0.60 (0.28, 1.27)		
p-value [1]	0.18		
Unadjusted Inverse Odds Ratio (95% CI)	0.50 (0.19, 1.34)		
p-value [1]	0.17		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.04, 0.31)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.66 (0.31, 1.40)		
p-value [2]	0.28		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

Table 2.1413: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Ab Discomfort) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	40 (66.7%)	28 (80.0%)	68 (71.6%)
Last participation date < Day 134 in RT Phase	15 (25.0%)	7 (20.0%)	22 (23.2%)
Last participation date >= Day 134 and Ab Discomfort Score at Week 20 not available	1 (1.7%)	0	1 (1.1%)
>0% increase from baseline at Week 20	10 (16.7%)	13 (37.1%)	23 (24.2%)
<50% reduction from baseline at Week 20	20 (33.3%)	18 (51.4%)	38 (40.0%)
Return Rate (%)	76%	82%	78%
Number of Subjects in Risk	51	32	83
Return Rate in Risk (%)	98%	100%	99%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

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Table 2.1413: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Ab Discomfort) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Ab Discomfort Symptom Score at Week 24			
Subjects Evaluable at Week 24, n	58	35	93
Ab Discomfort Score = 0 at baseline and Ab Discomfort Score >0 or missing at Week 24	2 (3.4%)	4 (11.4%)	6 (6.5%)
Responder, n(%)	22 (37.9%)	4 (11.4%)	26 (28.0%)
95% Exact CI	0.2551, 0.5163	0.0320, 0.2674	0.1914, 0.3822
Proportion Difference - Stratified CMH Method (95% CI)	0.26 (0.08, 0.44)		
p-value	0.005		
Proportion Difference - Unstratified CMH Method (95% CI)	0.27 (0.10, 0.43)		
p-value	0.002		
Proportion Difference - Unstratified Exact Method (95% CI)	0.27 (0.05, 0.46)		
p-value	0.008		
Unadjusted Inverse Relative Risk (95% CI)	0.30 (0.11, 0.80)		
p-value [1]	0.016		
Unadjusted Inverse Odds Ratio (95% CI)	0.21 (0.07, 0.68)		
p-value [1]	0.009		
Unadjusted Absolute Risk Difference (95% CI)	0.27 (0.10, 0.43)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.31 (0.12, 0.83)		
p-value [2]	0.019		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

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Table 2.1413: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Ab Discomfort) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	36 (62.1%)	31 (88.6%)	67 (72.0%)
Last participation date < Day 162 in RT Phase	18 (31.0%)	7 (20.0%)	25 (26.9%)
Last participation date >= Day 162 and Ab Discomfort Score at Week 24 not available	1 (1.7%)	3 (8.6%)	4 (4.3%)
>0% increase from baseline at Week 24	8 (13.8%)	14 (40.0%)	22 (23.7%)
<50% reduction from baseline at Week 24	15 (25.9%)	19 (54.3%)	34 (36.6%)
Return Rate (%)	71%	74%	72%
Number of Subjects in Risk	48	32	80
Return Rate in Risk (%)	98%	91%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

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Table 2.1412: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Early Satiety) by Every 4 Weeks

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Early Satiety Symptom Score Status			
Missing Early Satiety Score at baseline (excluded from rate calculation)	0	0	0
Early Satiety Score = 0 at baseline	8 (12.1%)	10 (25.6%)	18 (17.1%)
Early Satiety Score > 0 at baseline	58 (87.9%)	29 (74.4%)	87 (82.9%)
Response Rate of Early Satiety Symptom Score at Week 4			
Subjects Evaluable at Week 4, n	61	31	92
Early Satiety Score = 0 at baseline and Early Satiety Score >0 or missing at Week 4	3 (4.9%)	2 (6.5%)	5 (5.4%)
Responder, n(%)	14 (23.0%)	3 (9.7%)	17 (18.5%)
95% Exact CI	0.1315, 0.3550	0.0204, 0.2575	0.1115, 0.2793
Proportion Difference - Stratified CMH Method (95% CI)	0.13 (-0.03, 0.30)		
p-value	0.11		
Proportion Difference - Unstratified CMH Method (95% CI)	0.13 (-0.02, 0.29)		
p-value	0.093		
Proportion Difference - Unstratified Exact Method (95% CI)	0.13 (-0.09, 0.34)		
p-value	0.16		
Unadjusted Inverse Relative Risk (95% CI)	0.42 (0.13, 1.36)		
p-value [1]	0.15		
Unadjusted Inverse Odds Ratio (95% CI)	0.36 (0.09, 1.36)		
p-value [1]	0.13		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.02, 0.28)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.41 (0.14, 1.24)		
p-value [2]	0.11		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.1412: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Early Satiety) by Every 4 Weeks

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	47 (77.0%)	28 (90.3%)	75 (81.5%)
Last participation date < Day 21 in RT Phase	0	2 (6.5%)	2 (2.2%)
Last participation date >= Day 21 and Early Satiety Score at Week 4 not available	0	0	0
>0% increase from baseline at Week 4	22 (36.1%)	14 (45.2%)	36 (39.1%)
<50% reduction from baseline at Week 4	44 (72.1%)	24 (77.4%)	68 (73.9%)
Return Rate (%)	100%	95%	98%
Number of Subjects in Risk	66	37	103
Return Rate in Risk (%)	100%	100%	100%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.1412: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Early Satiety) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Early Satiety Symptom Score at Week 8			
Subjects Evaluable at Week 8, n	62	32	94
Early Satiety Score = 0 at baseline and Early Satiety Score >0 or missing at Week 8	4 (6.5%)	3 (9.4%)	7 (7.4%)
Responder, n(%)	21 (33.9%)	5 (15.6%)	26 (27.7%)
95% Exact CI	0.2233, 0.4701	0.0528, 0.3279	0.1893, 0.3785
Proportion Difference - Stratified CMH Method (95% CI)	0.17 (-0.02, 0.36)		
p-value	0.071		
Proportion Difference - Unstratified CMH Method (95% CI)	0.18 (0.01, 0.36)		
p-value	0.043		
Proportion Difference - Unstratified Exact Method (95% CI)	0.18 (-0.03, 0.39)		
p-value	0.088		
Unadjusted Inverse Relative Risk (95% CI)	0.46 (0.19, 1.11)		
p-value [1]	0.084		
Unadjusted Inverse Odds Ratio (95% CI)	0.36 (0.12, 1.07)		
p-value [1]	0.067		
Unadjusted Absolute Risk Difference (95% CI)	0.18 (0.01, 0.35)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

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Table 2.1412: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Early Satiety) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	41 (66.1%)	27 (84.4%)	68 (72.3%)
Last participation date < Day 50 in RT Phase	5 (8.1%)	3 (9.4%)	8 (8.5%)
Last participation date >= Day 50 and Early Satiety Score at Week 8 not available	2 (3.2%)	1 (3.1%)	3 (3.2%)
>0% increase from baseline at Week 8	17 (27.4%)	13 (40.6%)	30 (31.9%)
<50% reduction from baseline at Week 8	31 (50.0%)	21 (65.6%)	52 (55.3%)
Return Rate (%)	89%	90%	90%
Number of Subjects in Risk	61	36	97
Return Rate in Risk (%)	97%	97%	97%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

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Table 2.1412: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Early Satiety) by Every 4 Weeks

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Early Satiety Symptom Score at Week 12			
Subjects Evaluable at Week 12, n	62	33	95
Early Satiety Score = 0 at baseline and Early Satiety Score >0 or missing at Week 12	4 (6.5%)	4 (12.1%)	8 (8.4%)
Responder, n(%)	23 (37.1%)	5 (15.2%)	28 (29.5%)
95% Exact CI	0.2516, 0.5031	0.0511, 0.3190	0.2056, 0.3971
Proportion Difference - Stratified CMH Method (95% CI)	0.22 (0.03, 0.40)		
p-value	0.023		
Proportion Difference - Unstratified CMH Method (95% CI)	0.22 (0.04, 0.40)		
p-value	0.015		
Proportion Difference - Unstratified Exact Method (95% CI)	0.22 (0.01, 0.42)		
p-value	0.033		
Unadjusted Inverse Relative Risk (95% CI)	0.41 (0.17, 0.97)		
p-value [1]	0.044		
Unadjusted Inverse Odds Ratio (95% CI)	0.30 (0.10, 0.89)		
p-value [1]	0.030		
Unadjusted Absolute Risk Difference (95% CI)	0.22 (0.05, 0.39)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.1412: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Early Satiety) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	39 (62.9%)	28 (84.8%)	67 (70.5%)
Last participation date < Day 78 in RT Phase	7 (11.3%)	6 (18.2%)	13 (13.7%)
Last participation date >= Day 78 and Early Satiety Score at Week 12 not available	2 (3.2%)	0	2 (2.1%)
>0% increase from baseline at Week 12	13 (21.0%)	13 (39.4%)	26 (27.4%)
<50% reduction from baseline at Week 12	27 (43.5%)	19 (57.6%)	46 (48.4%)
Return Rate (%)	86%	85%	86%
Number of Subjects in Risk	59	33	92
Return Rate in Risk (%)	97%	100%	98%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

GSK Oncology

Study GS-US-352-1214

Table 2.1412: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Early Satiety) by Every 4 Weeks

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Early Satiety Symptom Score at Week 16			
Subjects Evaluable at Week 16, n	62	33	95
Early Satiety Score = 0 at baseline and Early Satiety Score >0 or missing at Week 16	4 (6.5%)	4 (12.1%)	8 (8.4%)
Responder, n(%)	22 (35.5%)	4 (12.1%)	26 (27.4%)
95% Exact CI	0.2374, 0.4866	0.0340, 0.2820	0.1872, 0.3748
Proportion Difference - Stratified CMH Method (95% CI)	0.25 (0.07, 0.43)		
p-value	0.007		
Proportion Difference - Unstratified CMH Method (95% CI)	0.23 (0.07, 0.40)		
p-value	0.006		
Proportion Difference - Unstratified Exact Method (95% CI)	0.23 (0.02, 0.43)		
p-value	0.016		
Unadjusted Inverse Relative Risk (95% CI)	0.34 (0.13, 0.91)		
p-value [1]	0.031		
Unadjusted Inverse Odds Ratio (95% CI)	0.25 (0.08, 0.81)		
p-value [1]	0.020		
Unadjusted Absolute Risk Difference (95% CI)	0.23 (0.07, 0.40)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

GSK Oncology

Study GS-US-352-1214

Table 2.1412: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Early Satiety) by Every 4 Weeks

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	40 (64.5%)	29 (87.9%)	69 (72.6%)
Last participation date < Day 106 in RT Phase	10 (16.1%)	7 (21.2%)	17 (17.9%)
Last participation date >= Day 106 and Early Satiety Score at Week 16 not available	4 (6.5%)	0	4 (4.2%)
>0% increase from baseline at Week 16	10 (16.1%)	12 (36.4%)	22 (23.2%)
<50% reduction from baseline at Week 16	22 (35.5%)	20 (60.6%)	42 (44.2%)
Return Rate (%)	79%	82%	80%
Number of Subjects in Risk	56	32	88
Return Rate in Risk (%)	93%	100%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.1412: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Early Satiety) by Every 4 Weeks

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Early Satiety Symptom Score at Week 20			
Subjects Evaluable at Week 20, n	63	33	96
Early Satiety Score = 0 at baseline and Early Satiety Score >0 or missing at Week 20	5 (7.9%)	4 (12.1%)	9 (9.4%)
Responder, n(%)	19 (30.2%)	7 (21.2%)	26 (27.1%)
95% Exact CI	0.1923, 0.4302	0.0898, 0.3891	0.1852, 0.3711
Proportion Difference - Stratified CMH Method (95% CI)		0.11 (-0.09, 0.30)	
p-value	0.29		
Proportion Difference - Unstratified CMH Method (95% CI)		0.09 (-0.09, 0.27)	
p-value	0.34		
Proportion Difference - Unstratified Exact Method (95% CI)		0.09 (-0.12, 0.30)	
p-value	0.47		
Unadjusted Inverse Relative Risk (95% CI)		0.70 (0.33, 1.50)	
p-value [1]	0.36		
Unadjusted Inverse Odds Ratio (95% CI)		0.62 (0.23, 1.68)	
p-value [1]	0.35		
Unadjusted Absolute Risk Difference (95% CI)		0.09 (-0.09, 0.27)	
Adjusted Inverse Relative Risk (95% CI) [2]		NE	
p-value [2]	NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.1412: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Early Satiety) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	44 (69.8%)	26 (78.8%)	70 (72.9%)
Last participation date < Day 134 in RT Phase	15 (23.8%)	7 (21.2%)	22 (22.9%)
Last participation date >= Day 134 and Early Satiety Score at Week 20 not available	1 (1.6%)	0	1 (1.0%)
>0% increase from baseline at Week 20	12 (19.0%)	9 (27.3%)	21 (21.9%)
<50% reduction from baseline at Week 20	23 (36.5%)	17 (51.5%)	40 (41.7%)
Return Rate (%)	76%	82%	78%
Number of Subjects in Risk	51	32	83
Return Rate in Risk (%)	98%	100%	99%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

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Table 2.1412: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Early Satiety) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Early Satiety Symptom Score at Week 24			
Subjects Evaluable at Week 24, n	62	34	96
Early Satiety Score = 0 at baseline and Early Satiety Score >0 or missing at Week 24	4 (6.5%)	5 (14.7%)	9 (9.4%)
Responder, n(%)	18 (29.0%)	7 (20.6%)	25 (26.0%)
95% Exact CI	0.1820, 0.4195	0.0870, 0.3790	0.1762, 0.3600
Proportion Difference - Stratified CMH Method (95% CI)	0.10 (-0.08, 0.29)		
p-value	0.28		
Proportion Difference - Unstratified CMH Method (95% CI)	0.08 (-0.10, 0.27)		
p-value	0.36		
Proportion Difference - Unstratified Exact Method (95% CI)	0.08 (-0.13, 0.29)		
p-value	0.47		
Unadjusted Inverse Relative Risk (95% CI)	0.71 (0.33, 1.53)		
p-value [1]	0.38		
Unadjusted Inverse Odds Ratio (95% CI)	0.63 (0.23, 1.72)		
p-value [1]	0.37		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.09, 0.26)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

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Table 2.1412: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Early Satiety) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	44 (71.0%)	27 (79.4%)	71 (74.0%)
Last participation date < Day 162 in RT Phase	18 (29.0%)	7 (20.6%)	25 (26.0%)
Last participation date >= Day 162 and Early Satiety Score at Week 24 not available	1 (1.6%)	3 (8.8%)	4 (4.2%)
>0% increase from baseline at Week 24	12 (19.4%)	8 (23.5%)	20 (20.8%)
<50% reduction from baseline at Week 24	22 (35.5%)	15 (44.1%)	37 (38.5%)
Return Rate (%)	71%	74%	72%
Number of Subjects in Risk	48	32	80
Return Rate in Risk (%)	98%	91%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

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Study GS-US-352-1214

Table 2.1411: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Tiredness) by Every 4 Weeks

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Tiredness Symptom Score Status			
Missing Tiredness Score at baseline (excluded from rate calculation)	0	0	0
Tiredness Score = 0 at baseline	2 (3.0%)	3 (7.7%)	5 (4.8%)
Tiredness Score > 0 at baseline	64 (97.0%)	36 (92.3%)	100 (95.2%)
Response Rate of Tiredness Symptom Score at Week 4			
Subjects Evaluable at Week 4, n	66	38	104
Tiredness Score = 0 at baseline and Tiredness Score >0 or missing at Week 4	2 (3.0%)	2 (5.3%)	4 (3.8%)
Responder, n(%)	6 (9.1%)	3 (7.9%)	9 (8.7%)
95% Exact CI	0.0341, 0.1874	0.0166, 0.2138	0.0403, 0.1579
Proportion Difference - Stratified CMH Method (95% CI)	0.01 (-0.13, 0.14)		
p-value	0.93		
Proportion Difference - Unstratified CMH Method (95% CI)	0.01 (-0.10, 0.13)		
p-value	0.84		
Proportion Difference - Unstratified Exact Method (95% CI)	0.01 (-0.19, 0.21)		
p-value	1.00		
Unadjusted Inverse Relative Risk (95% CI)	0.87 (0.23, 3.27)		
p-value [1]	0.83		
Unadjusted Inverse Odds Ratio (95% CI)	0.86 (0.20, 3.64)		
p-value [1]	0.83		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.10, 0.12)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.93 (0.26, 3.29)		
p-value [2]	0.91		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.1411: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Tiredness) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	60 (90.9%)	35 (92.1%)	95 (91.3%)
Last participation date < Day 21 in RT Phase	0	2 (5.3%)	2 (1.9%)
Last participation date >= Day 21 and Tiredness Score at Week 4 not available	0	0	0
>0% increase from baseline at Week 4	29 (43.9%)	15 (39.5%)	44 (42.3%)
<50% reduction from baseline at Week 4	58 (87.9%)	31 (81.6%)	89 (85.6%)
Return Rate (%)	100%	95%	98%
Number of Subjects in Risk	66	37	103
Return Rate in Risk (%)	100%	100%	100%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

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Study GS-US-352-1214

Table 2.1411: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Tiredness) by Every 4 Weeks

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Tiredness Symptom Score at Week 8			
Subjects Evaluable at Week 8, n	66	38	104
Tiredness Score = 0 at baseline and Tiredness Score >0 or missing at Week 8	2 (3.0%)	2 (5.3%)	4 (3.8%)
Responder, n(%)	15 (22.7%)	4 (10.5%)	19 (18.3%)
95% Exact CI	0.1331, 0.3470	0.0294, 0.2480	0.1137, 0.2705
Proportion Difference - Stratified CMH Method (95% CI)		0.10 (-0.06, 0.26)	
p-value	0.22		
Proportion Difference - Unstratified CMH Method (95% CI)		0.12 (-0.02, 0.27)	
p-value	0.10		
Proportion Difference - Unstratified Exact Method (95% CI)		0.12 (-0.08, 0.32)	
p-value	0.19		
Unadjusted Inverse Relative Risk (95% CI)		0.46 (0.17, 1.30)	
p-value [1]	0.14		
Unadjusted Inverse Odds Ratio (95% CI)		0.40 (0.12, 1.31)	
p-value [1]	0.13		
Unadjusted Absolute Risk Difference (95% CI)		0.12 (-0.02, 0.26)	
Adjusted Inverse Relative Risk (95% CI) [2]		NE	
p-value [2]	NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.1411: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Tiredness) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	51 (77.3%)	34 (89.5%)	85 (81.7%)
Last participation date < Day 50 in RT Phase	5 (7.6%)	3 (7.9%)	8 (7.7%)
Last participation date >= Day 50 and Tiredness Score at Week 8 not available	2 (3.0%)	1 (2.6%)	3 (2.9%)
>0% increase from baseline at Week 8	20 (30.3%)	10 (26.3%)	30 (28.8%)
<50% reduction from baseline at Week 8	42 (63.6%)	28 (73.7%)	70 (67.3%)
Return Rate (%)	89%	90%	90%
Number of Subjects in Risk	61	36	97
Return Rate in Risk (%)	97%	97%	97%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

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Table 2.1411: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Tiredness) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Tiredness Symptom Score at Week 12			
Subjects Evaluable at Week 12, n	65	38	103
Tiredness Score = 0 at baseline and Tiredness Score >0 or missing at Week 12	1 (1.5%)	2 (5.3%)	3 (2.9%)
Responder, n(%)	18 (27.7%)	2 (5.3%)	20 (19.4%)
95% Exact CI	0.1731, 0.4019	0.0064, 0.1775	0.1228, 0.2838
Proportion Difference - Stratified CMH Method (95% CI)	0.20 (0.05, 0.36)		
p-value	0.012		
Proportion Difference - Unstratified CMH Method (95% CI)	0.22 (0.09, 0.36)		
p-value	0.001		
Proportion Difference - Unstratified Exact Method (95% CI)	0.22 (0.02, 0.41)		
p-value	0.005		
Unadjusted Inverse Relative Risk (95% CI)	0.19 (0.05, 0.77)		
p-value [1]	0.021		
Unadjusted Inverse Odds Ratio (95% CI)	0.15 (0.03, 0.67)		
p-value [1]	0.013		
Unadjusted Absolute Risk Difference (95% CI)	0.22 (0.09, 0.35)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.21 (0.05, 0.91)		
p-value [2]	0.037		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

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Table 2.1411: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Tiredness) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	47 (72.3%)	36 (94.7%)	83 (80.6%)
Last participation date < Day 78 in RT Phase	7 (10.8%)	6 (15.8%)	13 (12.6%)
Last participation date >= Day 78 and Tiredness Score at Week 12 not available	2 (3.1%)	0	2 (1.9%)
>0% increase from baseline at Week 12	16 (24.6%)	13 (34.2%)	29 (28.2%)
<50% reduction from baseline at Week 12	37 (56.9%)	28 (73.7%)	65 (63.1%)
Return Rate (%)	86%	85%	86%
Number of Subjects in Risk	59	33	92
Return Rate in Risk (%)	97%	100%	98%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

GSK Oncology
Study GS-US-352-1214

Table 2.1411: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Tiredness) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Tiredness Symptom Score at Week 16			
Subjects Evaluable at Week 16, n	65	38	103
Tiredness Score = 0 at baseline and Tiredness Score >0 or missing at Week 16	1 (1.5%)	2 (5.3%)	3 (2.9%)
Responder, n(%)	14 (21.5%)	3 (7.9%)	17 (16.5%)
95% Exact CI	0.1231, 0.3349	0.0166, 0.2138	0.0992, 0.2511
Proportion Difference - Stratified CMH Method (95% CI)		0.15 (-0.01, 0.30)	
p-value		0.063	
Proportion Difference - Unstratified CMH Method (95% CI)		0.14 (0.00, 0.27)	
p-value		0.051	
Proportion Difference - Unstratified Exact Method (95% CI)		0.14 (-0.06, 0.33)	
p-value		0.099	
Unadjusted Inverse Relative Risk (95% CI)		0.37 (0.11, 1.19)	
p-value [1]		0.096	
Unadjusted Inverse Odds Ratio (95% CI)		0.31 (0.08, 1.17)	
p-value [1]		0.084	
Unadjusted Absolute Risk Difference (95% CI)		0.14 (0.00, 0.27)	
Adjusted Inverse Relative Risk (95% CI) [2]		0.34 (0.11, 1.11)	
p-value [2]		0.075	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

GSK Oncology
Study GS-US-352-1214

Table 2.1411: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Tiredness) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	51 (78.5%)	35 (92.1%)	86 (83.5%)
Last participation date < Day 106 in RT Phase	10 (15.4%)	7 (18.4%)	17 (16.5%)
Last participation date >= Day 106 and Tiredness Score at Week 16 not available	4 (6.2%)	0	4 (3.9%)
>0% increase from baseline at Week 16	15 (23.1%)	14 (36.8%)	29 (28.2%)
<50% reduction from baseline at Week 16	36 (55.4%)	26 (68.4%)	62 (60.2%)
Return Rate (%)	79%	82%	80%
Number of Subjects in Risk	56	32	88
Return Rate in Risk (%)	93%	100%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

GSK Oncology
Study GS-US-352-1214

Table 2.1411: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Tiredness) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Tiredness Symptom Score at Week 20			
Subjects Evaluable at Week 20, n	65	38	103
Tiredness Score = 0 at baseline and Tiredness Score >0 or missing at Week 20	1 (1.5%)	2 (5.3%)	3 (2.9%)
Responder, n(%)	18 (27.7%)	4 (10.5%)	22 (21.4%)
95% Exact CI	0.1731, 0.4019	0.0294, 0.2480	0.1390, 0.3053
Proportion Difference - Stratified CMH Method (95% CI)	0.17 (0.00, 0.33)		
p-value	0.047		
Proportion Difference - Unstratified CMH Method (95% CI)	0.17 (0.02, 0.32)		
p-value	0.026		
Proportion Difference - Unstratified Exact Method (95% CI)	0.17 (-0.03, 0.36)		
p-value	0.048		
Unadjusted Inverse Relative Risk (95% CI)	0.38 (0.14, 1.04)		
p-value [1]	0.060		
Unadjusted Inverse Odds Ratio (95% CI)	0.31 (0.10, 0.99)		
p-value [1]	0.048		
Unadjusted Absolute Risk Difference (95% CI)	0.17 (0.03, 0.32)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.39 (0.14, 1.06)		
p-value [2]	0.064		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

GSK Oncology
Study GS-US-352-1214

Table 2.1411: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Tiredness) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	47 (72.3%)	34 (89.5%)	81 (78.6%)
Last participation date < Day 134 in RT Phase	15 (23.1%)	7 (18.4%)	22 (21.4%)
Last participation date >= Day 134 and Tiredness Score at Week 20 not available	1 (1.5%)	0	1 (1.0%)
>0% increase from baseline at Week 20	15 (23.1%)	11 (28.9%)	26 (25.2%)
<50% reduction from baseline at Week 20	30 (46.2%)	25 (65.8%)	55 (53.4%)
Return Rate (%)	76%	82%	78%
Number of Subjects in Risk	51	32	83
Return Rate in Risk (%)	98%	100%	99%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

GSK Oncology

Study GS-US-352-1214

Table 2.1411: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Tiredness) by Every 4 Weeks

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Response Rate of Tiredness Symptom Score at Week 24			
Subjects Evaluable at Week 24, n	65	38	103
Tiredness Score = 0 at baseline and Tiredness Score >0 or missing at Week 24	1 (1.5%)	2 (5.3%)	3 (2.9%)
Responder, n(%)	19 (29.2%)	2 (5.3%)	21 (20.4%)
95% Exact CI	0.1860, 0.4183	0.0064, 0.1775	0.1309, 0.2946
Proportion Difference - Stratified CMH Method (95% CI)		0.24 (0.09, 0.38)	
p-value		0.001	
Proportion Difference - Unstratified CMH Method (95% CI)		0.24 (0.10, 0.38)	
p-value		<0.001	
Proportion Difference - Unstratified Exact Method (95% CI)		0.24 (0.04, 0.43)	
p-value		0.004	
Unadjusted Inverse Relative Risk (95% CI)		0.18 (0.04, 0.73)	
p-value [1]		0.016	
Unadjusted Inverse Odds Ratio (95% CI)		0.13 (0.03, 0.62)	
p-value [1]		0.010	
Unadjusted Absolute Risk Difference (95% CI)		0.24 (0.11, 0.37)	
Adjusted Inverse Relative Risk (95% CI) [2]		0.18 (0.05, 0.70)	
p-value [2]		0.014	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.

Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).

Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.1411: Analysis of Response Rate (improvement, 50% criterion) in TSS Item Score (Tiredness) by Every 4 Weeks
Randomized Treatment Phase
ITT-Anemic Analysis Set

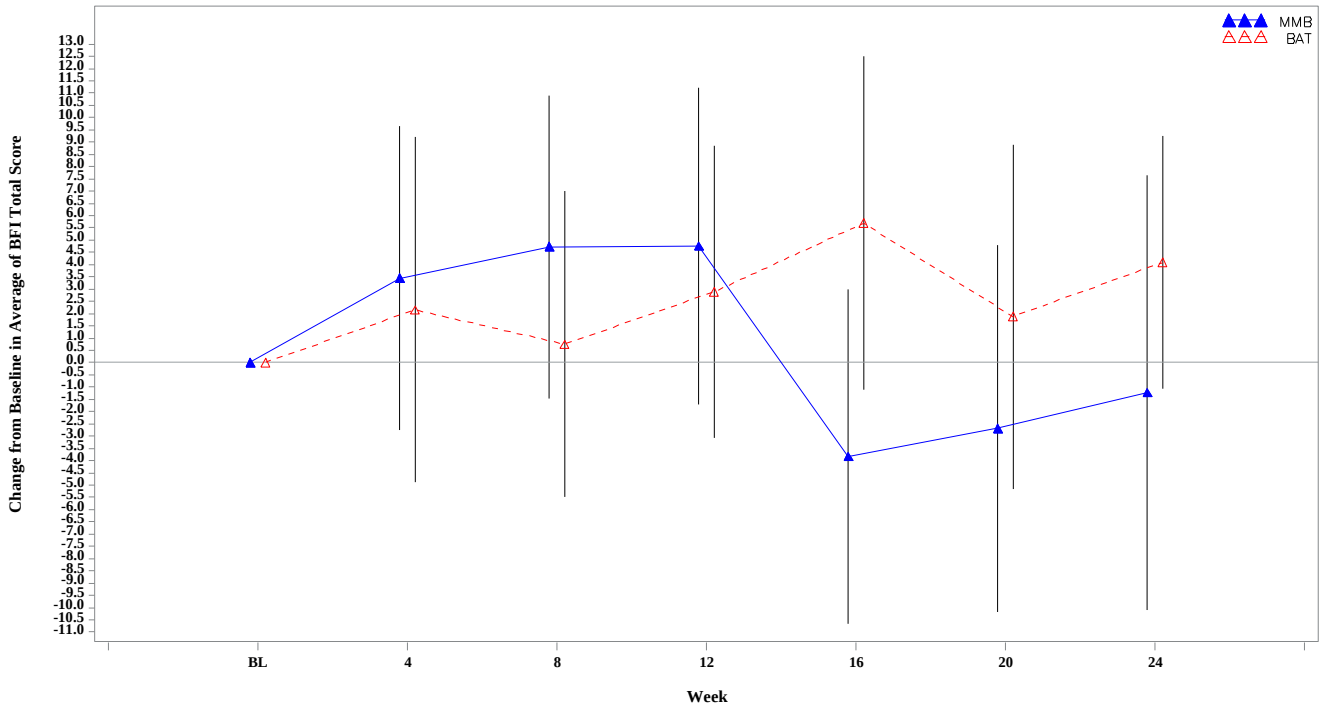
	MMB (N=66)	BAT (N=39)	Total (N=105)
Non-Responder, n(%)	46 (70.8%)	36 (94.7%)	82 (79.6%)
Last participation date < Day 162 in RT Phase	18 (27.7%)	7 (18.4%)	25 (24.3%)
Last participation date >= Day 162 and Tiredness Score at Week 24 not available	1 (1.5%)	3 (7.9%)	4 (3.9%)
>0% increase from baseline at Week 24	16 (24.6%)	14 (36.8%)	30 (29.1%)
<50% reduction from baseline at Week 24	26 (40.0%)	25 (65.8%)	51 (49.5%)
Return Rate (%)	71%	74%	72%
Number of Subjects in Risk	48	32	80
Return Rate in Risk (%)	98%	91%	95%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with item score > 0 at baseline or (score = 0 at baseline and [score > 0 or missing]).
Subjects with item score = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Data Extracted: CRF data: 25JUN2019

2.5 Fatigue

GSK Oncology
Study GS-US-352-1214

Figure 2.7701.01: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Brief Total Inventory Score Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set

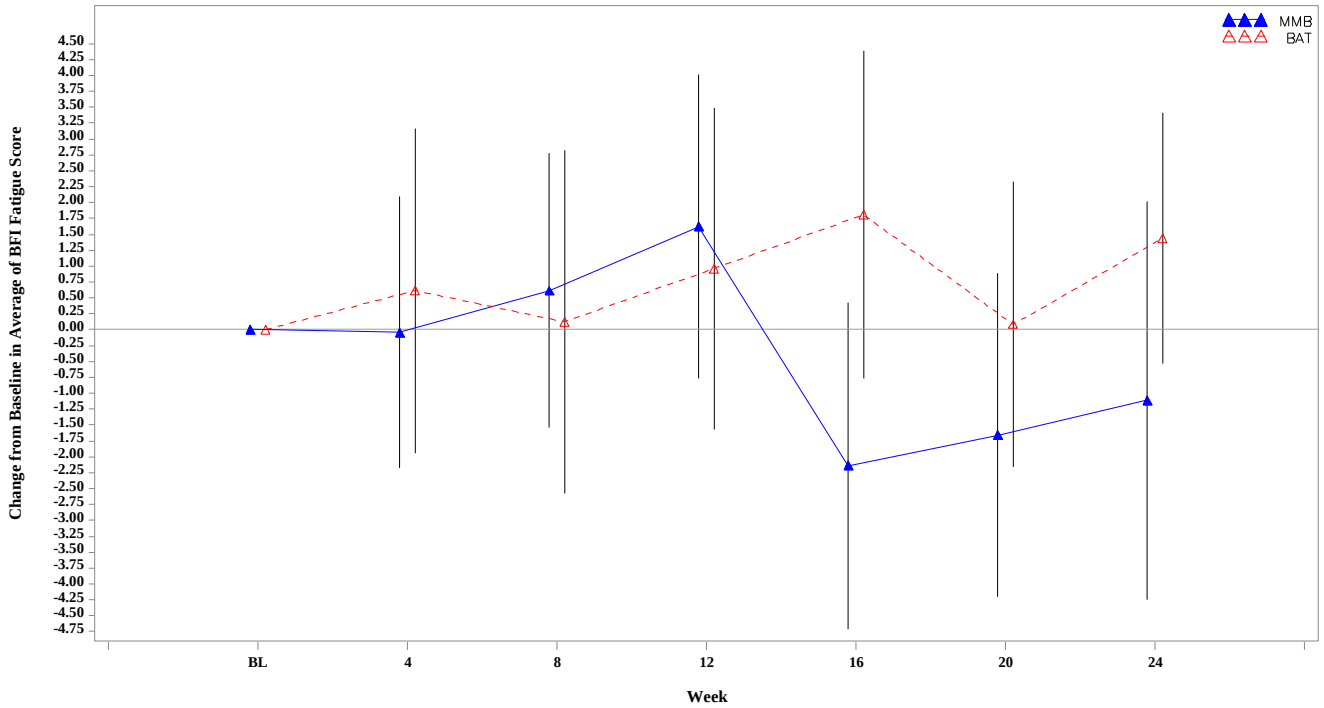


MMB (n)	50	45	44	37	36	32	27
BAT (n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/adhoc/2023/G-BA-Dec2023/prod/tfls/g-spv-line_adhoc.sas V.03.05 Output file: g-bfi-line-chg-rt.pdf 24JAN2024:21:23

Figure 2.7701.03: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Brief Fatigue Inventory Score Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set

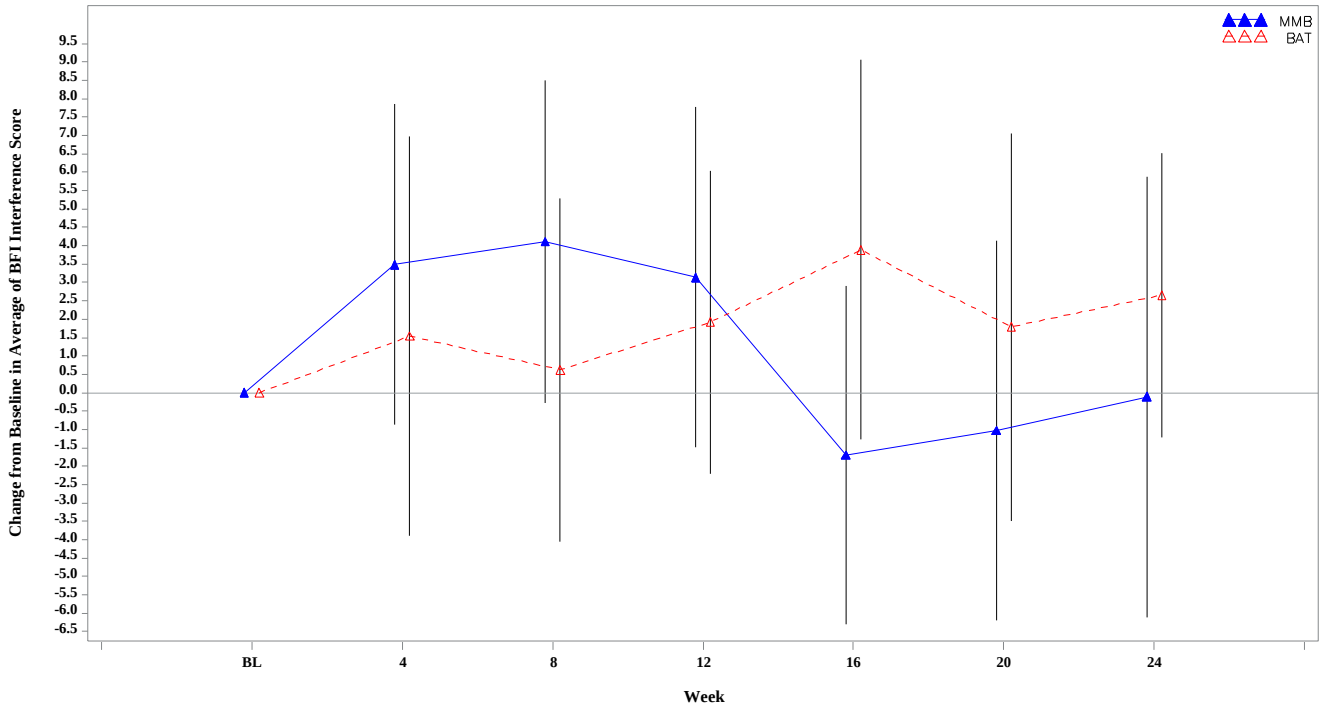


MMB (n)	50	45	44	37	36	32	27
BAT (n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/adhoc/2023/G-BA-Dec2023/prod/tfls/g-spv-line_adhoc.sas V.03.05 Output file: g-bfif-line-chg-rt.pdf 24JAN2024:21:24

Figure 2.7701.03: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in Brief Interference Inventory Score Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set



MMB (n)	50	45	44	37	36	32	27
BAT (n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/adhoc/2023/G-BA-Dec2023/prod/tfls/g-spv-line_adhoc.sas V.03.05 Output file: g-bfii-line-chg-rt.pdf 24JAN2024:21:24

Table 2.7701.01: Analysis of Brief Total Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
BFISCORE - BFI Total Score at Baseline		
n	50	29
Mean (SD)	34.2 (24.43)	40.4 (23.48)
Median	29.0	37.0
Q1, Q3	13.0, 55.0	29.0, 58.0
Min, Max	0.0, 84.0	0.0, 87.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
BFISCORE - BFI Total Score at Week 4		
n	60	31
Mean (SD)	33.9 (22.22)	43.3 (23.36)
Median	32.5	45.0
Q1, Q3	14.5, 53.0	24.0, 62.0
Min, Max	0.0, 77.0	3.0, 90.0
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in BFI Total Score at Week 4 from Baseline		
n	45	26
Mean (SD)	3.4 (20.60)	2.2 (17.45)
Median	2.0	0.0
Q1, Q3	-7.0, 14.0	-8.0, 6.0
Min, Max	-50.0, 56.0	-29.0, 42.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.01: Analysis of Brief Total Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Change from Baseline at Week 4		
n [1]	47	27
n [2]	45	26
MMRM: Least Squares Mean [SE] (95% CI)	3.27 [2.65] (-2.01, 8.55)	4.10 [3.19] (-2.26, 10.46)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.83 [4.12] (-9.06, 7.40)	
MMRM: P-value	0.84	
Corrected Hedges' g (95% CI)	-0.048 (-0.531, 0.435)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.42	
Percent Change in BFI Total Score at Week 4 from Baseline		
n	43	25
Mean (SD)	46.0 (125.86)	37.3 (122.14)
Median	4.8	-2.7
Q1, Q3	-17.0, 56.0	-17.5, 24.0
Min, Max	-100.0, 466.7	-63.0, 540.0
Difference in Percent Change from Baseline at Week 4		
n [1]	44	26
n [2]	43	25
MMRM: Least Squares Mean [SE] (95% CI)	48.41 [17.37] (13.72, 83.11)	45.98 [21.03] (3.98, 87.99)
MMRM: Least Squares Mean Difference [SE] (95% CI)	2.43 [27.32] (-52.15, 57.00)	
MMRM: P-value	0.93	
Corrected Hedges' g (95% CI)	0.022 (-0.471, 0.515)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.65	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.01: Analysis of Brief Total Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
BFISCORE - BFI Total Score at Week 8		
n	57	27
Mean (SD)	34.3 (22.39)	41.6 (19.06)
Median	31.0	40.0
Q1, Q3	18.0, 52.0	30.0, 53.0
Min, Max	0.0, 76.0	7.0, 89.0
Return Rate (%)	86%	69%
Number of Subjects in Risk	61	36
Return Rate in Risk (%)	93%	75%
Change in BFI Total Score at Week 8 from Baseline		
n	44	24
Mean (SD)	4.7 (20.36)	0.8 (14.77)
Median	4.0	1.0
Q1, Q3	-8.5, 15.5	-5.0, 8.5
Min, Max	-59.0, 63.0	-29.0, 29.0
Difference in Change from Baseline at Week 8		
n [1]	47	27
n [2]	44	24
MMRM: Least Squares Mean [SE] (95% CI)	4.93 [2.62] (-0.29, 10.16)	3.98 [3.19] (-2.39, 10.35)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.96 [4.09] (-7.21, 9.13)	
MMRM: P-value	0.82	
Corrected Hedges' g (95% CI)	0.056 (-0.441, 0.554)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.91	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.01: Analysis of Brief Total Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in BFI Total Score at Week 8 from Baseline		
n	42	23
Mean (SD)	54.4 (128.29)	58.9 (168.93)
Median	8.2	1.7
Q1, Q3	-25.0, 90.5	-13.0, 40.0
Min, Max	-100.0, 525.0	-51.4, 600.0
Difference in Percent Change from Baseline at Week 8		
n [1]	44	26
n [2]	42	23
MMRM: Least Squares Mean [SE] (95% CI)	54.46 [19.45] (15.60, 93.31)	66.34 [24.20] (17.99, 114.69)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-11.88 [31.06] (-73.93, 50.17)	
MMRM: P-value	0.70	
Corrected Hedges' g (95% CI)	-0.096 (-0.604, 0.413)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.71	
BFISCORE - BFI Total Score at Week 12		
n	51	30
Mean (SD)	32.8 (22.54)	42.3 (23.12)
Median	29.0	36.5
Q1, Q3	16.0, 52.0	25.0, 60.0
Min, Max	0.0, 80.0	4.0, 90.0
Return Rate (%)	77%	77%
Number of Subjects in Risk	59	33
Return Rate in Risk (%)	86%	91%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.01: Analysis of Brief Total Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in BFI Total Score at Week 12 from Baseline		
n	37	26
Mean (SD)	4.8 (19.36)	2.9 (14.77)
Median	7.0	4.5
Q1, Q3	-11.0, 17.0	-4.0, 14.0
Min, Max	-38.0, 41.0	-30.0, 26.0
Difference in Change from Baseline at Week 12		
n [1]	47	27
n [2]	37	26
MMRM: Least Squares Mean [SE] (95% CI)	3.54 [2.88] (-2.21, 9.30)	5.39 [3.29] (-1.17, 11.96)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.85 [4.35] (-10.53, 6.83)	
MMRM: P-value	0.67	
Corrected Hedges' g (95% CI)	-0.106 (-0.608, 0.396)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.78	
Percent Change in BFI Total Score at Week 12 from Baseline		
n	35	25
Mean (SD)	54.9 (124.45)	85.9 (250.42)
Median	19.0	8.6
Q1, Q3	-38.5, 125.0	-21.4, 48.0
Min, Max	-100.0, 372.7	-53.8, 1100.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.01: Analysis of Brief Total Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 12		
n [1]	44	26
n [2]	35	25
MMRM: Least Squares Mean [SE] (95% CI)	59.04 [26.00] (7.09, 110.99)	96.12 [31.99] (32.22, 160.03)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-37.09 [41.22] (-119.43, 45.26)	
MMRM: P-value	0.37	
Corrected Hedges' g (95% CI)	-0.234 (-0.749, 0.281)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.96	
BFISCORE - BFI Total Score at Week 16		
n	48	30
Mean (SD)	27.4 (21.64)	42.1 (23.45)
Median	20.0	36.5
Q1, Q3	11.5, 44.0	29.0, 63.0
Min, Max	0.0, 81.0	0.0, 90.0
Return Rate (%)	73%	77%
Number of Subjects in Risk	56	33
Return Rate in Risk (%)	86%	91%
Change in BFI Total Score at Week 16 from Baseline		
n	36	26
Mean (SD)	-3.8 (20.21)	5.7 (16.87)
Median	1.0	3.0
Q1, Q3	-18.5, 8.5	-5.0, 17.0
Min, Max	-48.0, 31.0	-24.0, 51.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.01: Analysis of Brief Total Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Change from Baseline at Week 16		
n [1]	47	27
n [2]	36	26
MMRM: Least Squares Mean [SE] (95% CI)	-0.62 [2.96] (-6.54, 5.29)	8.30 [3.43] (1.45, 15.15)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-8.92 [4.51] (-17.92, 0.08)	
MMRM: P-value	0.052	
Corrected Hedges' g (95% CI)	-0.499 (-1.011, 0.013)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.21	
Percent Change in BFI Total Score at Week 16 from Baseline		
n	34	25
Mean (SD)	14.8 (97.92)	68.5 (172.31)
Median	2.0	5.4
Q1, Q3	-57.6, 41.2	-9.0, 48.0
Min, Max	-100.0, 277.8	-44.1, 675.0
Difference in Percent Change from Baseline at Week 16		
n [1]	44	26
n [2]	34	25
MMRM: Least Squares Mean [SE] (95% CI)	23.83 [20.01] (-16.14, 63.79)	78.46 [23.19] (32.13, 124.79)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-54.63 [30.61] (-115.78, 6.51)	
MMRM: P-value	0.079	
Corrected Hedges' g (95% CI)	-0.463 (-0.986, 0.060)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.16	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.01: Analysis of Brief Total Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
BFISCORE - BFI Total Score at Week 20		
n	44	29
Mean (SD)	27.0 (17.38)	41.9 (24.24)
Median	24.0	38.0
Q1, Q3	17.0, 36.5	28.0, 60.0
Min, Max	0.0, 75.0	0.0, 88.0
Return Rate (%)	67%	74%
Number of Subjects in Risk	51	32
Return Rate in Risk (%)	86%	91%
Change in BFI Total Score at Week 20 from Baseline		
n	32	24
Mean (SD)	-2.7 (20.77)	1.9 (16.62)
Median	-2.0	1.0
Q1, Q3	-11.5, 12.0	-5.5, 6.5
Min, Max	-54.0, 30.0	-26.0, 44.0
Difference in Change from Baseline at Week 20		
n [1]	47	27
n [2]	32	24
MMRM: Least Squares Mean [SE] (95% CI)	1.21 [2.92] (-4.61, 7.03)	5.63 [3.33] (-1.02, 12.29)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-4.42 [4.41] (-13.22, 4.37)	
MMRM: P-value	0.32	
Corrected Hedges' g (95% CI)	-0.265 (-0.797, 0.266)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.38	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.01: Analysis of Brief Total Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in BFI Total Score at Week 20 from Baseline		
n	30	23
Mean (SD)	21.7 (100.40)	17.1 (72.53)
Median	-15.3	1.1
Q1, Q3	-36.0, 56.5	-18.4, 46.9
Min, Max	-100.0, 300.0	-100.0, 260.0
Difference in Percent Change from Baseline at Week 20		
n [1]	44	26
n [2]	30	23
MMRM: Least Squares Mean [SE] (95% CI)	26.02 [17.52] (-8.98, 61.02)	47.86 [19.20] (9.52, 86.21)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-21.84 [25.97] (-73.73, 30.04)	
MMRM: P-value	0.40	
Corrected Hedges' g (95% CI)	-0.228 (-0.773, 0.317)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.27	
BFISCORE - BFI Total Score at Week 24		
n	41	29
Mean (SD)	28.0 (20.53)	44.7 (24.82)
Median	24.0	41.0
Q1, Q3	16.0, 39.0	25.0, 66.0
Min, Max	0.0, 80.0	0.0, 89.0
Return Rate (%)	62%	74%
Number of Subjects in Risk	48	31
Return Rate in Risk (%)	85%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.01: Analysis of Brief Total Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in BFI Total Score at Week 24 from Baseline		
n	27	23
Mean (SD)	-1.2 (22.41)	4.1 (11.90)
Median	3.0	3.0
Q1, Q3	-11.0, 13.0	-5.0, 11.0
Min, Max	-58.0, 31.0	-16.0, 35.0
Difference in Change from Baseline at Week 24		
n [1]	47	27
n [2]	27	23
MMRM: Least Squares Mean [SE] (95% CI)	0.59 [3.00] (-5.39, 6.57)	9.35 [3.30] (2.77, 15.93)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-8.76 [4.43] (-17.61, 0.09)	
MMRM: P-value	0.052	
Corrected Hedges' g (95% CI)	-0.550 (-1.116, 0.017)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.84	
Percent Change in BFI Total Score at Week 24 from Baseline		
n	25	22
Mean (SD)	33.2 (100.39)	19.6 (62.51)
Median	14.3	5.4
Q1, Q3	-35.6, 76.5	-12.5, 31.0
Min, Max	-100.0, 300.0	-100.0, 220.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.01: Analysis of Brief Total Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 24		
n [1]	44	26
n [2]	25	22
MMRM: Least Squares Mean [SE] (95% CI)	30.30 [17.08] (-3.82, 64.42)	52.93 [18.05] (16.86, 88.99)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-22.63 [24.86] (-72.29, 27.04)	
MMRM: P-value	0.37	
Corrected Hedges' g (95% CI)	-0.262 (-0.837, 0.314)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.99	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.02: Analysis of Brief Fatigue Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
BFIFATIG - BFI Fatigue Score at Baseline		
n	50	29
Mean (SD)	12.7 (8.78)	15.8 (8.02)
Median	11.0	17.0
Q1, Q3	5.0, 20.0	11.0, 21.0
Min, Max	0.0, 28.0	0.0, 30.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
BFIFATIG - BFI Fatigue Score at Week 4		
n	60	31
Mean (SD)	12.0 (7.23)	16.3 (7.71)
Median	10.0	17.0
Q1, Q3	7.0, 18.0	10.0, 23.0
Min, Max	0.0, 26.0	0.0, 30.0
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in BFI Fatigue Score at Week 4 from Baseline		
n	45	26
Mean (SD)	0.0 (7.11)	0.6 (6.32)
Median	0.0	-0.5
Q1, Q3	-3.0, 4.0	-4.0, 4.0
Min, Max	-18.0, 17.0	-9.0, 18.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.02: Analysis of Brief Fatigue Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Change from Baseline at Week 4		
n [1]	47	27
n [2]	45	26
MMRM: Least Squares Mean [SE] (95% CI)	-0.57 [0.93] (-2.43, 1.29)	1.37 [1.13] (-0.89, 3.62)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.94 [1.46] (-4.85, 0.98)	
MMRM: P-value	0.19	
Corrected Hedges' g (95% CI)	-0.316 (-0.801, 0.170)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.72	
Percent Change in BFI Fatigue Score at Week 4 from Baseline		
n	42	23
Mean (SD)	20.7 (96.46)	5.3 (55.75)
Median	-2.3	-5.6
Q1, Q3	-31.8, 36.4	-25.0, 19.0
Min, Max	-100.0, 400.0	-66.7, 200.0
Difference in Percent Change from Baseline at Week 4		
n [1]	43	24
n [2]	42	23
MMRM: Least Squares Mean [SE] (95% CI)	18.02 [12.90] (-7.76, 43.81)	11.92 [16.19] (-20.45, 44.30)
MMRM: Least Squares Mean Difference [SE] (95% CI)	6.10 [20.83] (-35.55, 47.75)	
MMRM: P-value	0.77	
Corrected Hedges' g (95% CI)	0.074 (-0.435, 0.582)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.66	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.02: Analysis of Brief Fatigue Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
BFIFATIG - BFI Fatigue Score at Week 8		
n	57	27
Mean (SD)	12.0 (7.79)	16.1 (6.60)
Median	12.0	17.0
Q1, Q3	7.0, 18.0	12.0, 21.0
Min, Max	0.0, 27.0	4.0, 30.0
Return Rate (%)	86%	69%
Number of Subjects in Risk	61	36
Return Rate in Risk (%)	93%	75%
Change in BFI Fatigue Score at Week 8 from Baseline		
n	44	24
Mean (SD)	0.6 (7.09)	0.1 (6.38)
Median	0.0	-1.0
Q1, Q3	-3.0, 4.0	-4.5, 4.0
Min, Max	-17.0, 21.0	-9.0, 17.0
Difference in Change from Baseline at Week 8		
n [1]	47	27
n [2]	44	24
MMRM: Least Squares Mean [SE] (95% CI)	0.19 [0.93] (-1.66, 2.05)	1.35 [1.14] (-0.92, 3.62)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.16 [1.46] (-4.08, 1.76)	
MMRM: P-value	0.43	
Corrected Hedges' g (95% CI)	-0.192 (-0.690, 0.307)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.97	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.02: Analysis of Brief Fatigue Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in BFI Fatigue Score at Week 8 from Baseline		
n	41	21
Mean (SD)	36.3 (104.84)	3.1 (52.56)
Median	0.0	-8.7
Q1, Q3	-24.0, 44.4	-25.0, 5.9
Min, Max	-100.0, 350.0	-46.7, 200.0
Difference in Percent Change from Baseline at Week 8		
n [1]	43	24
n [2]	41	21
MMRM: Least Squares Mean [SE] (95% CI)	32.55 [13.17] (6.21, 58.90)	13.60 [16.93] (-20.26, 47.46)
MMRM: Least Squares Mean Difference [SE] (95% CI)	18.95 [21.55] (-24.14, 62.04)	
MMRM: P-value	0.38	
Corrected Hedges' g (95% CI)	0.228 (-0.300, 0.755)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.60	
BFIFATIG - BFI Fatigue Score at Week 12		
n	51	30
Mean (SD)	12.3 (7.90)	16.7 (7.53)
Median	12.0	15.0
Q1, Q3	6.0, 19.0	12.0, 24.0
Min, Max	0.0, 30.0	3.0, 30.0
Return Rate (%)	77%	77%
Number of Subjects in Risk	59	33
Return Rate in Risk (%)	86%	91%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.02: Analysis of Brief Fatigue Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in BFI Fatigue Score at Week 12 from Baseline		
n	37	26
Mean (SD)	1.6 (7.16)	1.0 (6.26)
Median	0.0	0.5
Q1, Q3	-3.0, 4.0	-3.0, 6.0
Min, Max	-16.0, 15.0	-13.0, 13.0
Difference in Change from Baseline at Week 12		
n [1]	47	27
n [2]	37	26
MMRM: Least Squares Mean [SE] (95% CI)	0.62 [1.09] (-1.56, 2.80)	2.15 [1.25] (-0.35, 4.64)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.53 [1.66] (-4.83, 1.78)	
MMRM: P-value	0.36	
Corrected Hedges' g (95% CI)	-0.230 (-0.733, 0.273)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.91	
Percent Change in BFI Fatigue Score at Week 12 from Baseline		
n	34	23
Mean (SD)	64.7 (173.73)	9.2 (54.03)
Median	0.0	0.0
Q1, Q3	-25.0, 50.0	-25.0, 23.5
Min, Max	-100.0, 650.0	-54.2, 200.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.02: Analysis of Brief Fatigue Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 12		
n [1]	43	24
n [2]	34	23
MMRM: Least Squares Mean [SE] (95% CI)	60.05 [20.97] (18.12, 101.99)	20.46 [26.42] (-32.36, 73.28)
MMRM: Least Squares Mean Difference [SE] (95% CI)	39.59 [33.79] (-27.97, 107.15)	
MMRM: P-value	0.25	
Corrected Hedges' g (95% CI)	0.315 (-0.218, 0.847)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.79	
BFIFATIG - BFI Fatigue Score at Week 16		
n	48	30
Mean (SD)	9.8 (7.38)	16.5 (7.52)
Median	8.0	16.0
Q1, Q3	4.0, 17.5	12.0, 24.0
Min, Max	0.0, 27.0	0.0, 30.0
Return Rate (%)	73%	77%
Number of Subjects in Risk	56	33
Return Rate in Risk (%)	86%	91%
Change in BFI Fatigue Score at Week 16 from Baseline		
n	36	26
Mean (SD)	-2.1 (7.59)	1.8 (6.38)
Median	-1.0	0.0
Q1, Q3	-6.0, 2.0	-3.0, 7.0
Min, Max	-27.0, 12.0	-11.0, 17.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.02: Analysis of Brief Fatigue Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Change from Baseline at Week 16		
n [1]	47	27
n [2]	36	26
MMRM: Least Squares Mean [SE] (95% CI)	-1.59 [1.02] (-3.63, 0.44)	3.05 [1.18] (0.69, 5.41)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-4.64 [1.56] (-7.75, -1.53)	
MMRM: P-value	0.004	
Corrected Hedges' g (95% CI)	-0.754 (-1.276, -0.232)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.054	
Percent Change in BFI Fatigue Score at Week 16 from Baseline		
n	33	23
Mean (SD)	4.6 (84.42)	8.4 (44.66)
Median	-12.5	0.0
Q1, Q3	-50.0, 16.7	-16.7, 22.2
Min, Max	-100.0, 300.0	-66.7, 140.0
Difference in Percent Change from Baseline at Week 16		
n [1]	43	24
n [2]	33	23
MMRM: Least Squares Mean [SE] (95% CI)	11.25 [12.07] (-12.88, 35.38)	19.33 [14.36] (-9.39, 48.05)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-8.08 [18.86] (-45.79, 29.63)	
MMRM: P-value	0.67	
Corrected Hedges' g (95% CI)	-0.115 (-0.648, 0.418)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.24	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.02: Analysis of Brief Fatigue Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
BFIFATIG - BFI Fatigue Score at Week 20		
n	44	29
Mean (SD)	10.2 (6.32)	16.0 (8.09)
Median	10.0	14.0
Q1, Q3	6.0, 14.5	11.0, 23.0
Min, Max	0.0, 24.0	0.0, 30.0
Return Rate (%)	67%	74%
Number of Subjects in Risk	51	32
Return Rate in Risk (%)	86%	91%
Change in BFI Fatigue Score at Week 20 from Baseline		
n	32	24
Mean (SD)	-1.7 (7.05)	0.1 (5.32)
Median	0.0	0.0
Q1, Q3	-5.5, 3.0	-3.0, 2.0
Min, Max	-19.0, 9.0	-10.0, 13.0
Difference in Change from Baseline at Week 20		
n [1]	47	27
n [2]	32	24
MMRM: Least Squares Mean [SE] (95% CI)	-0.89 [0.98] (-2.84, 1.06)	1.77 [1.11] (-0.43, 3.98)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.66 [1.47] (-5.59, 0.28)	
MMRM: P-value	0.075	
Corrected Hedges' g (95% CI)	-0.479 (-1.015, 0.058)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.36	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.02: Analysis of Brief Fatigue Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in BFI Fatigue Score at Week 20 from Baseline		
n	29	22
Mean (SD)	0.1 (81.88)	3.6 (32.21)
Median	-20.0	-3.8
Q1, Q3	-43.8, 22.2	-18.8, 9.5
Min, Max	-100.0, 300.0	-41.7, 76.5
Difference in Percent Change from Baseline at Week 20		
n [1]	43	24
n [2]	29	22
MMRM: Least Squares Mean [SE] (95% CI)	6.32 [11.76] (-17.21, 29.84)	17.18 [13.38] (-9.59, 43.94)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-10.86 [17.91] (-46.67, 24.95)	
MMRM: P-value	0.55	
Corrected Hedges' g (95% CI)	-0.169 (-0.725, 0.386)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.20	
BFIFATIG - BFI Fatigue Score at Week 24		
n	41	29
Mean (SD)	9.9 (7.13)	17.6 (8.50)
Median	9.0	17.0
Q1, Q3	6.0, 12.0	12.0, 25.0
Min, Max	0.0, 27.0	0.0, 30.0
Return Rate (%)	62%	74%
Number of Subjects in Risk	48	31
Return Rate in Risk (%)	85%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.02: Analysis of Brief Fatigue Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in BFI Fatigue Score at Week 24 from Baseline		
n	27	23
Mean (SD)	-1.1 (7.91)	1.4 (4.57)
Median	0.0	0.0
Q1, Q3	-6.0, 6.0	-2.0, 4.0
Min, Max	-21.0, 12.0	-6.0, 13.0
Difference in Change from Baseline at Week 24		
n [1]	47	27
n [2]	27	23
MMRM: Least Squares Mean [SE] (95% CI)	-1.36 [1.02] (-3.39, 0.67)	3.55 [1.12] (1.31, 5.79)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-4.91 [1.51] (-7.93, -1.89)	
MMRM: P-value	0.002	
Corrected Hedges' g (95% CI)	-0.906 (-1.489, -0.322)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.52	
Percent Change in BFI Fatigue Score at Week 24 from Baseline		
n	24	21
Mean (SD)	18.9 (96.01)	9.9 (28.17)
Median	-4.5	0.0
Q1, Q3	-50.0, 52.1	-11.1, 23.8
Min, Max	-100.0, 300.0	-28.6, 76.5

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.02: Analysis of Brief Fatigue Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 24		
n [1]	43	24
n [2]	24	21
MMRM: Least Squares Mean [SE] (95% CI)	13.76 [11.50] (-9.23, 36.75)	23.36 [12.85] (-2.33, 49.05)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-9.60 [17.37] (-44.33, 25.12)	
MMRM: P-value	0.58	
Corrected Hedges' g (95% CI)	-0.164 (-0.751, 0.423)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.44	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.03: Analysis of Brief Interference Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
BFIINTER - BFI Interference Score at Baseline		
n	50	29
Mean (SD)	21.6 (16.39)	24.7 (16.66)
Median	17.0	21.0
Q1, Q3	6.0, 36.0	11.0, 37.0
Min, Max	0.0, 57.0	0.0, 57.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
BFIINTER - BFI Interference Score at Week 4		
n	60	31
Mean (SD)	22.0 (15.84)	27.0 (16.74)
Median	19.5	23.0
Q1, Q3	7.5, 35.0	16.0, 39.0
Min, Max	0.0, 56.0	0.0, 60.0
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in BFI Interference Score at Week 4 from Baseline		
n	45	26
Mean (SD)	3.5 (14.53)	1.5 (13.46)
Median	2.0	0.0
Q1, Q3	-4.0, 11.0	-4.0, 5.0
Min, Max	-32.0, 42.0	-20.0, 34.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.03: Analysis of Brief Interference Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Change from Baseline at Week 4		
n [1]	47	27
n [2]	45	26
MMRM: Least Squares Mean [SE] (95% CI)	3.79 [1.90] (0.00, 7.58)	2.66 [2.29] (-1.91, 7.22)
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.14 [2.96] (-4.77, 7.04)	
MMRM: P-value	0.70	
Corrected Hedges' g (95% CI)	0.091 (-0.392, 0.574)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.35	
Percent Change in BFI Interference Score at Week 4 from Baseline		
n	41	24
Mean (SD)	41.5 (137.86)	28.2 (88.65)
Median	0.0	0.0
Q1, Q3	-35.1, 66.7	-25.6, 34.1
Min, Max	-100.0, 700.0	-71.4, 242.9
Difference in Percent Change from Baseline at Week 4		
n [1]	42	25
n [2]	41	24
MMRM: Least Squares Mean [SE] (95% CI)	47.92 [18.99] (9.95, 85.89)	35.60 [22.32] (-9.03, 80.22)
MMRM: Least Squares Mean Difference [SE] (95% CI)	12.32 [29.21] (-46.10, 70.74)	
MMRM: P-value	0.67	
Corrected Hedges' g (95% CI)	0.104 (-0.400, 0.608)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.77	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.03: Analysis of Brief Interference Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
BFIINTER - BFI Interference Score at Week 8		
n	57	27
Mean (SD)	22.3 (15.12)	25.5 (13.69)
Median	20.0	23.0
Q1, Q3	14.0, 33.0	18.0, 37.0
Min, Max	0.0, 53.0	0.0, 59.0
Return Rate (%)	86%	69%
Number of Subjects in Risk	61	36
Return Rate in Risk (%)	93%	75%
Change in BFI Interference Score at Week 8 from Baseline		
n	44	24
Mean (SD)	4.1 (14.42)	0.6 (11.06)
Median	1.0	-0.5
Q1, Q3	-4.5, 11.5	-4.5, 3.5
Min, Max	-42.0, 42.0	-20.0, 23.0
Difference in Change from Baseline at Week 8		
n [1]	47	27
n [2]	44	24
MMRM: Least Squares Mean [SE] (95% CI)	4.70 [1.87] (0.97, 8.42)	2.68 [2.28] (-1.86, 7.22)
MMRM: Least Squares Mean Difference [SE] (95% CI)	2.01 [2.92] (-3.81, 7.83)	
MMRM: P-value	0.49	
Corrected Hedges' g (95% CI)	0.166 (-0.332, 0.664)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.59	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.03: Analysis of Brief Interference Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in BFI Interference Score at Week 8 from Baseline		
n	40	22
Mean (SD)	68.3 (153.07)	29.4 (80.88)
Median	6.9	-4.3
Q1, Q3	-22.9, 104.2	-18.2, 75.0
Min, Max	-100.0, 700.0	-57.9, 200.0
Difference in Percent Change from Baseline at Week 8		
n [1]	42	25
n [2]	40	22
MMRM: Least Squares Mean [SE] (95% CI)	72.38 [19.41] (33.58, 111.19)	44.85 [23.25] (-1.65, 91.34)
MMRM: Least Squares Mean Difference [SE] (95% CI)	27.54 [30.21] (-32.87, 87.95)	
MMRM: P-value	0.37	
Corrected Hedges' g (95% CI)	0.230 (-0.292, 0.752)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.54	
BFIINTER - BFI Interference Score at Week 12		
n	51	30
Mean (SD)	20.5 (15.25)	25.6 (16.11)
Median	18.0	23.5
Q1, Q3	7.0, 34.0	15.0, 40.0
Min, Max	0.0, 51.0	0.0, 60.0
Return Rate (%)	77%	77%
Number of Subjects in Risk	59	33
Return Rate in Risk (%)	86%	91%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.03: Analysis of Brief Interference Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in BFI Interference Score at Week 12 from Baseline		
n	37	26
Mean (SD)	3.1 (13.89)	1.9 (10.19)
Median	4.0	2.0
Q1, Q3	-7.0, 14.0	-4.0, 10.0
Min, Max	-28.0, 39.0	-18.0, 21.0
Difference in Change from Baseline at Week 12		
n [1]	47	27
n [2]	37	26
MMRM: Least Squares Mean [SE] (95% CI)	2.78 [1.98] (-1.17, 6.73)	3.31 [2.26] (-1.19, 7.82)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.53 [2.98] (-6.48, 5.42)	
MMRM: P-value	0.86	
Corrected Hedges' g (95% CI)	-0.044 (-0.546, 0.457)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.72	
Percent Change in BFI Interference Score at Week 12 from Baseline		
n	33	24
Mean (SD)	51.6 (114.67)	34.9 (90.86)
Median	25.0	4.9
Q1, Q3	-40.0, 114.3	-14.3, 55.0
Min, Max	-100.0, 320.0	-88.9, 275.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.03: Analysis of Brief Interference Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 12		
n [1]	42	25
n [2]	33	24
MMRM: Least Squares Mean [SE] (95% CI)	56.70 [17.11] (22.48, 90.92)	42.27 [18.54] (5.20, 79.33)
MMRM: Least Squares Mean Difference [SE] (95% CI)	14.43 [25.04] (-35.64, 64.51)	
MMRM: P-value	0.57	
Corrected Hedges' g (95% CI)	0.149 (-0.377, 0.676)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.79	
BFIINTER - BFI Interference Score at Week 16		
n	48	30
Mean (SD)	17.6 (14.76)	25.6 (16.82)
Median	13.0	23.0
Q1, Q3	6.0, 27.5	17.0, 41.0
Min, Max	0.0, 54.0	0.0, 60.0
Return Rate (%)	73%	77%
Number of Subjects in Risk	56	33
Return Rate in Risk (%)	86%	91%
Change in BFI Interference Score at Week 16 from Baseline		
n	36	26
Mean (SD)	-1.7 (13.57)	3.9 (12.79)
Median	0.0	2.5
Q1, Q3	-11.0, 7.0	-1.0, 10.0
Min, Max	-30.0, 21.0	-22.0, 42.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.03: Analysis of Brief Interference Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Change from Baseline at Week 16		
n [1]	47	27
n [2]	36	26
MMRM: Least Squares Mean [SE] (95% CI)	0.87 [2.13] (-3.37, 5.12)	5.33 [2.46] (0.43, 10.24)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-4.46 [3.23] (-10.91, 1.99)	
MMRM: P-value	0.17	
Corrected Hedges' g (95% CI)	-0.347 (-0.856, 0.161)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.47	
Percent Change in BFI Interference Score at Week 16 from Baseline		
n	33	24
Mean (SD)	28.2 (118.05)	35.8 (111.59)
Median	0.0	5.3
Q1, Q3	-56.8, 50.0	-19.6, 44.7
Min, Max	-100.0, 333.3	-100.0, 350.0
Difference in Percent Change from Baseline at Week 16		
n [1]	42	25
n [2]	33	24
MMRM: Least Squares Mean [SE] (95% CI)	34.75 [19.52] (-4.29, 73.78)	42.88 [21.65] (-0.40, 86.17)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-8.14 [28.99] (-66.11, 49.84)	
MMRM: P-value	0.78	
Corrected Hedges' g (95% CI)	-0.073 (-0.599, 0.453)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.43	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.03: Analysis of Brief Interference Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
BFIINTER - BFI Interference Score at Week 20		
n	44	29
Mean (SD)	16.8 (11.97)	25.9 (16.73)
Median	14.0	22.0
Q1, Q3	8.5, 25.0	16.0, 39.0
Min, Max	0.0, 51.0	0.0, 58.0
Return Rate (%)	67%	74%
Number of Subjects in Risk	51	32
Return Rate in Risk (%)	86%	91%
Change in BFI Interference Score at Week 20 from Baseline		
n	32	24
Mean (SD)	-1.0 (14.34)	1.8 (12.48)
Median	0.0	1.0
Q1, Q3	-7.0, 9.0	-3.0, 6.0
Min, Max	-35.0, 22.0	-24.0, 31.0
Difference in Change from Baseline at Week 20		
n [1]	47	27
n [2]	32	24
MMRM: Least Squares Mean [SE] (95% CI)	1.74 [2.07] (-2.39, 5.88)	3.86 [2.34] (-0.81, 8.53)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.12 [3.11] (-8.32, 4.09)	
MMRM: P-value	0.50	
Corrected Hedges' g (95% CI)	-0.180 (-0.710, 0.351)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.48	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.03: Analysis of Brief Interference Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in BFI Interference Score at Week 20 from Baseline		
n	29	22
Mean (SD)	46.6 (133.28)	21.5 (77.57)
Median	-5.9	2.0
Q1, Q3	-31.3, 60.0	-20.6, 42.1
Min, Max	-100.0, 333.3	-100.0, 221.4
Difference in Percent Change from Baseline at Week 20		
n [1]	42	25
n [2]	29	22
MMRM: Least Squares Mean [SE] (95% CI)	49.39 [18.67] (12.05, 86.73)	39.52 [20.27] (-1.01, 80.04)
MMRM: Least Squares Mean Difference [SE] (95% CI)	9.87 [27.39] (-44.89, 64.64)	
MMRM: P-value	0.72	
Corrected Hedges' g (95% CI)	0.099 (-0.456, 0.653)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.33	
BFIINTER - BFI Interference Score at Week 24		
n	41	29
Mean (SD)	18.1 (13.99)	27.0 (17.15)
Median	18.0	25.0
Q1, Q3	7.0, 24.0	16.0, 42.0
Min, Max	0.0, 53.0	0.0, 59.0
Return Rate (%)	62%	74%
Number of Subjects in Risk	48	31
Return Rate in Risk (%)	85%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.03: Analysis of Brief Interference Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in BFI Interference Score at Week 24 from Baseline		
n	27	23
Mean (SD)	-0.1 (15.15)	2.7 (8.97)
Median	5.0	2.0
Q1, Q3	-6.0, 11.0	-2.0, 9.0
Min, Max	-37.0, 23.0	-16.0, 22.0
Difference in Change from Baseline at Week 24		
n [1]	47	27
n [2]	27	23
MMRM: Least Squares Mean [SE] (95% CI)	1.63 [2.12] (-2.59, 5.86)	5.68 [2.30] (1.09, 10.26)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-4.04 [3.11] (-10.24, 2.16)	
MMRM: P-value	0.20	
Corrected Hedges' g (95% CI)	-0.361 (-0.922, 0.199)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.89	
Percent Change in BFI Interference Score at Week 24 from Baseline		
n	24	21
Mean (SD)	48.2 (121.42)	23.6 (71.51)
Median	18.6	3.5
Q1, Q3	-45.0, 116.7	-10.7, 31.6
Min, Max	-100.0, 300.0	-100.0, 177.8

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.7701.03: Analysis of Brief Interference Inventory Score and Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Difference in Percent Change from Baseline at Week 24		
n [1]	42	25
n [2]	24	21
MMRM: Least Squares Mean [SE] (95% CI)	40.12 [17.61] (4.90, 75.34)	44.03 [18.17] (7.69, 80.36)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-3.90 [25.12] (-54.14, 46.33)	
MMRM: P-value	0.88	
Corrected Hedges' g (95% CI)	-0.045 (-0.631, 0.541)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.98	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

GSK Oncology

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Table 2.7419: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #19 at Week 24

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N = 66)	BAT (N = 39)	Total (N = 105)
BFI0101 - Fatigue Right Now at Week 24			
Responder, n(%)	7 (10.6%)	5 (12.8%)	12 (11.4%)
Unadjusted Inverse Relative Risk (95% CI)	1.21 (0.41, 3.55)		
p-value [1]	0.73		
Unadjusted Inverse Odds Ratio (95% CI)	1.24 (0.36, 4.21)		
p-value [1]	0.73		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.15, 0.11)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.23 (0.41, 3.69)		
p-value [2]	0.71		
Non-Responder, n(%)	59 (89.4%)	34 (87.2%)	93 (88.6%)
Non-missing	20 (30.3%)	18 (46.2%)	38 (36.2%)
Missing	39 (59.1%)	16 (41.0%)	55 (52.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.7420: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #20 at Week 24
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N = 66)	BAT (N = 39)	Total (N = 105)
BFI0102 - Usual Fatigue Level Past 24 Hours at Week 24			
Responder, n(%)	9 (13.6%)	3 (7.7%)	12 (11.4%)
Unadjusted Inverse Relative Risk (95% CI)	0.56 (0.16, 1.96)		
p-value [1]	0.37		
Unadjusted Inverse Odds Ratio (95% CI)	0.53 (0.13, 2.08)		
p-value [1]	0.36		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.06, 0.18)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.56 (0.16, 1.96)		
p-value [2]	0.36		
Non-Responder, n(%)	57 (86.4%)	36 (92.3%)	93 (88.6%)
Non-missing	18 (27.3%)	20 (51.3%)	38 (36.2%)
Missing	39 (59.1%)	16 (41.0%)	55 (52.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

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Table 2.7421: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #21 at Week 24
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N = 66)	BAT (N = 39)	Total (N = 105)
BFI0103 - Worst Fatigue Level Past 24 Hours at Week 24			
Responder, n(%)	9 (13.6%)	4 (10.3%)	13 (12.4%)
Unadjusted Inverse Relative Risk (95% CI)	0.75 (0.25, 2.28)		
p-value [1]	0.61		
Unadjusted Inverse Odds Ratio (95% CI)	0.72 (0.21, 2.53)		
p-value [1]	0.61		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.09, 0.16)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.74 (0.24, 2.23)		
p-value [2]	0.59		
Non-Responder, n(%)	57 (86.4%)	35 (89.7%)	92 (87.6%)
Non-missing	18 (27.3%)	19 (48.7%)	37 (35.2%)
Missing	39 (59.1%)	16 (41.0%)	55 (52.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.7422: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #22 at Week 24

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N = 66)	BAT (N = 39)	Total (N = 105)
BFI0104 - Interfered Activity Past 24 Hours at Week 24			
Responder, n(%)	9 (13.6%)	1 (2.6%)	10 (9.5%)
Unadjusted Inverse Relative Risk (95% CI)	0.19 (0.02, 1.43)		
p-value [1]	0.11		
Unadjusted Inverse Odds Ratio (95% CI)	0.17 (0.02, 1.37)		
p-value [1]	0.095		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (0.01, 0.21)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.20 (0.03, 1.43)		
p-value [2]	0.11		
Non-Responder, n(%)	57 (86.4%)	38 (97.4%)	95 (90.5%)
Non-missing	18 (27.3%)	22 (56.4%)	40 (38.1%)
Missing	39 (59.1%)	16 (41.0%)	55 (52.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.7423: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #23 at Week 24

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N = 66)	BAT (N = 39)	Total (N = 105)
BFI0105 - Interfered Mood Past 24 Hours at Week 24			
Responder, n(%)	8 (12.1%)	3 (7.7%)	11 (10.5%)
Unadjusted Inverse Relative Risk (95% CI)	0.63 (0.18, 2.25)		
p-value [1]	0.48		
Unadjusted Inverse Odds Ratio (95% CI)	0.60 (0.15, 2.43)		
p-value [1]	0.48		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.07, 0.16)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.68 (0.19, 2.44)		
p-value [2]	0.55		
Non-Responder, n(%)	58 (87.9%)	36 (92.3%)	94 (89.5%)
Non-missing	19 (28.8%)	20 (51.3%)	39 (37.1%)
Missing	39 (59.1%)	16 (41.0%)	55 (52.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.7424: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #24 at Week 24
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N = 66)	BAT (N = 39)	Total (N = 105)
BFI0106 - Interfered Walking Past 24 Hours at Week 24			
Responder, n(%)	5 (7.6%)	4 (10.3%)	9 (8.6%)
Unadjusted Inverse Relative Risk (95% CI)	1.35 (0.39, 4.74)		
p-value [1]	0.64		
Unadjusted Inverse Odds Ratio (95% CI)	1.39 (0.35, 5.54)		
p-value [1]	0.64		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.14, 0.09)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.23 (0.32, 4.68)		
p-value [2]	0.76		
Non-Responder, n(%)	61 (92.4%)	35 (89.7%)	96 (91.4%)
Non-missing	22 (33.3%)	19 (48.7%)	41 (39.0%)
Missing	39 (59.1%)	16 (41.0%)	55 (52.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.7425: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #25 at Week 24

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N = 66)	BAT (N = 39)	Total (N = 105)
BFI0107 - Interfered Work Past 24 Hours at Week 24			
Responder, n(%)	6 (9.1%)	1 (2.6%)	7 (6.7%)
Unadjusted Inverse Relative Risk (95% CI)	0.28 (0.04, 2.26)		
p-value [1]	0.23		
Unadjusted Inverse Odds Ratio (95% CI)	0.26 (0.03, 2.27)		
p-value [1]	0.22		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.02, 0.15)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Non-Responder, n(%)	60 (90.9%)	38 (97.4%)	98 (93.3%)
Non-missing	21 (31.8%)	22 (56.4%)	43 (41.0%)
Missing	39 (59.1%)	16 (41.0%)	55 (52.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

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Table 2.7426: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #26 at Week 24
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N = 66)	BAT (N = 39)	Total (N = 105)
BFI0108 - Interfered Relations Past 24 Hours at Week 24			
Responder, n(%)	4 (6.1%)	5 (12.8%)	9 (8.6%)
Unadjusted Inverse Relative Risk (95% CI)	2.12 (0.60, 7.41)		
p-value [1]	0.24		
Unadjusted Inverse Odds Ratio (95% CI)	2.28 (0.57, 9.06)		
p-value [1]	0.24		
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.19, 0.05)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.69 (0.51, 5.64)		
p-value [2]	0.39		
Non-Responder, n(%)	62 (93.9%)	34 (87.2%)	96 (91.4%)
Non-missing	23 (34.8%)	18 (46.2%)	41 (39.0%)
Missing	39 (59.1%)	16 (41.0%)	55 (52.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019
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Table 2.7427: Analysis of Response Rate (improvement, 15% criterion) in MPN-SAF Questionnaire Item #27 at Week 24

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N = 66)	BAT (N = 39)	Total (N = 105)
BFI0109 - Interfered Enjoyment Past 24 Hours at Week 24			
Responder, n(%)	5 (7.6%)	6 (15.4%)	11 (10.5%)
Unadjusted Inverse Relative Risk (95% CI)	2.03 (0.66, 6.22)		
p-value [1]	0.21		
Unadjusted Inverse Odds Ratio (95% CI)	2.22 (0.63, 7.82)		
p-value [1]	0.22		
Unadjusted Absolute Risk Difference (95% CI)	-0.08 (-0.21, 0.05)		
Adjusted Inverse Relative Risk (95% CI) [2]	2.10 (0.64, 6.87)		
p-value [2]	0.22		
Non-Responder, n(%)	61 (92.4%)	33 (84.6%)	94 (89.5%)
Non-missing	22 (33.3%)	17 (43.6%)	39 (37.1%)
Missing	39 (59.1%)	16 (41.0%)	55 (52.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

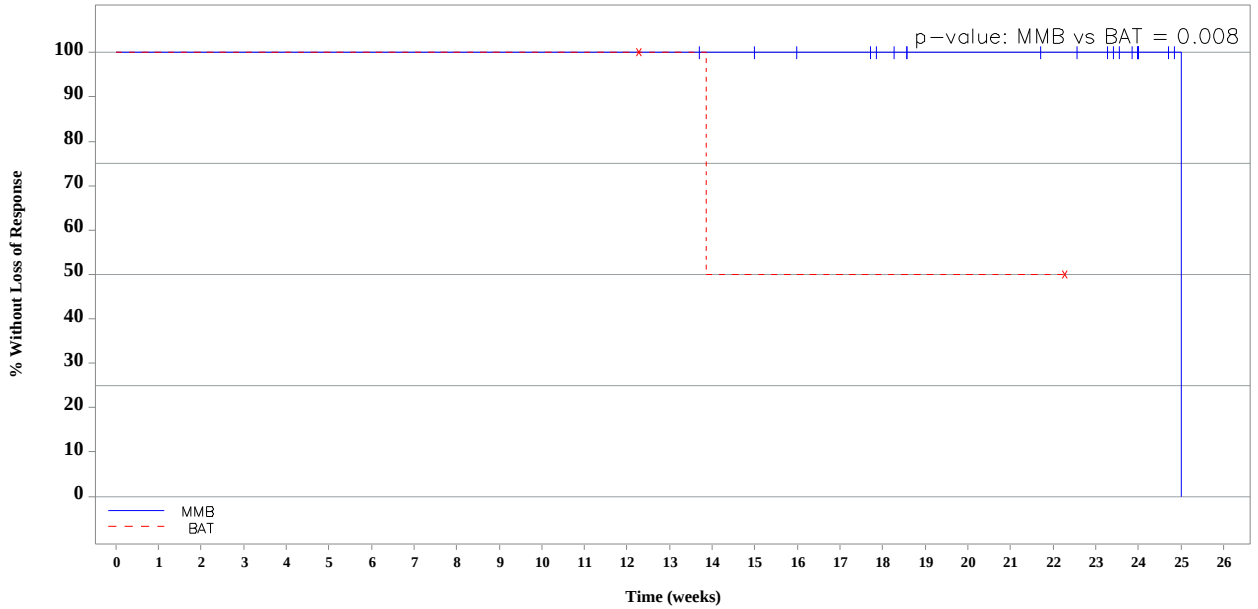
Data Extracted: CRF data: 25JUN2019

2.6 Transfusionen

2.6.1 TI

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Figure 2.2011: Kaplan-Meier Plot of Duration of RBC Transfusion Independent Response
Randomized Treatment Phase
ITT-Anemic Analysis Set who are not Transfusion Independent at baseline but at any Post-baseline



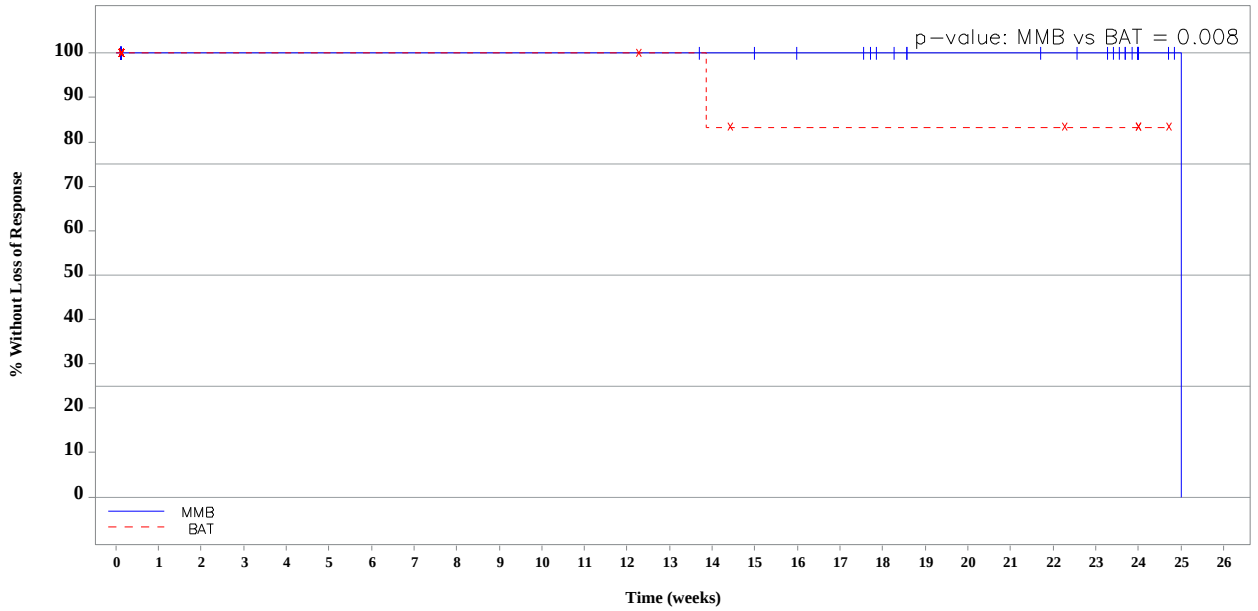
N at Risk (Events)

MMB	22 (0)	22 (0)	22 (0)	22 (0)	22 (0)	22 (0)	22 (0)	22 (0)	22 (0)	22 (0)	22 (0)	22 (0)	22 (0)	22 (0)	21 (0)	21 (0)	20 (0)	19 (0)	17 (0)	14 (0)	14 (0)	14 (0)	13 (0)	12 (0)	8 (0)	1 (1)	0 (1)
BAT	3 (0)	3 (0)	3 (0)	3 (0)	3 (0)	3 (0)	3 (0)	3 (0)	3 (0)	3 (0)	3 (0)	3 (0)	3 (0)	2 (0)	1 (1)	1 (1)	1 (1)	1 (1)	1 (1)	1 (1)	1 (1)	1 (1)	1 (1)	0 (1)	0 (1)	0 (1)	0 (1)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-dur-rbc-ti-tib.sas V.03.05 Output file: g-dur-rbc-ti-tib.pdf 25AUG2023:12:35

Figure 2.2201: Kaplan-Meier Plot of Duration of RBC Transfusion Independent Response
Randomized Treatment Phase
ITT-Anemic Analysis Set



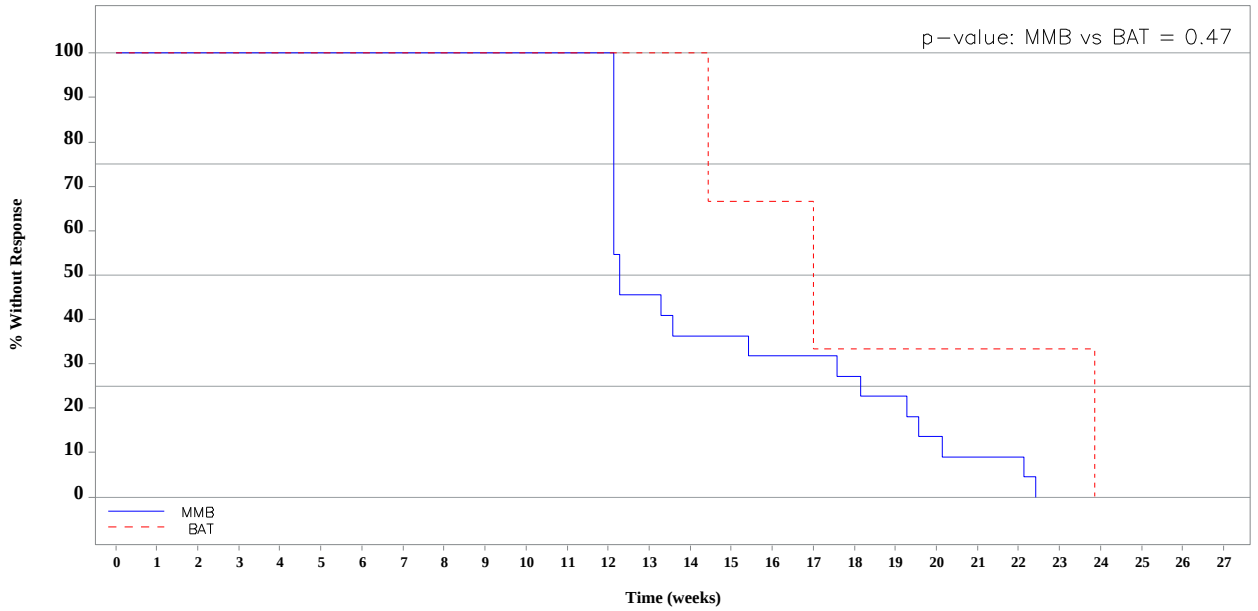
N at Risk (Events)

MMB	66 (0)	25 (0)	25 (0)	25 (0)	25 (0)	25 (0)	25 (0)	25 (0)	25 (0)	25 (0)	25 (0)	25 (0)	25 (0)	25 (0)	24 (0)	24 (0)	23 (0)	22 (0)	19 (0)	16 (0)	16 (0)	16 (0)	15 (0)	14 (0)	8 (0)	1 (1)	0 (1)
BAT	39 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	6 (0)	5 (1)	4 (1)	4 (1)	4 (1)	4 (1)	4 (1)	4 (1)	4 (1)	4 (1)	3 (1)	3 (1)	0 (1)	0 (1)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-dur-rbc-ti.sas V.03.05 Output file: g-dur-rbc-ti.pdf 25AUG2023:12:36

Figure 2.2111: Kaplan-Meier Plot of Time to RBC Transfusion Independent Response
Randomized Treatment Phase
ITT-Anemic Analysis Set who are not Transfusion Independent at baseline but at any Post-baseline



N at Risk (Events)

MMB	22 (0)	22 (0)	22 (0)	22 (0)	22 (0)	22 (0)	22 (0)	22 (0)	22 (0)	22 (0)	22 (0)	22 (0)	22 (0)	10 (12)	8 (14)	8 (14)	7 (15)	7 (15)	6 (16)	5 (17)	3 (19)	2 (20)	2 (20)	0 (22)	0 (22)	0 (22)	0 (22)	0 (22)
BAT	3 (0)	3 (0)	3 (0)	3 (0)	3 (0)	3 (0)	3 (0)	3 (0)	3 (0)	3 (0)	3 (0)	3 (0)	3 (0)	3 (0)	3 (0)	2 (1)	2 (1)	2 (2)	1 (2)	1 (2)	1 (2)	1 (2)	1 (2)	1 (2)	0 (3)	0 (3)	0 (3)	0 (3)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-tte-ti-tib.sas V.03.05 Output file: g-tte-ti-tib.pdf 25AUG2023:13:04

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Table 2.5201: Analysis of response rate of no Transfusion of Any Type for 24 weeks

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Any Type Transfusion Free Rate			
Responder, n(%)	12 (18.2%)	4 (10.3%)	16 (15.2%)
95% Exact CI	0.0976, 0.2961	0.0287, 0.2422	0.0897, 0.2356
Proportion Difference - Unstratified Exact Method (95% CI)	0.08 (-0.12, 0.27)		
p-value	0.40		
Unadjusted Inverse Relative Risk (95% CI)	0.56 (0.20, 1.63)		
p-value [1]	0.29		
Unadjusted Inverse Odds Ratio (95% CI)	0.51 (0.15, 1.72)		
p-value [1]	0.28		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.05, 0.21)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.47 (0.19, 1.21)		
p-value [2]	0.12		
Non-responder, n(%)	54 (81.8%)	35 (89.7%)	89 (84.8%)
Any Type Transfusion within 24 weeks	53 (80.3%)	33 (84.6%)	86 (81.9%)
Discontinued prior to week 24	1 (1.5%)	2 (5.1%)	3 (2.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.8602: Analysis of Duration of RBC Transfusion Independent Response by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Subjects with Event					
Loss of RBC Transfusion Independent Response, n(%)	0	0	1 (2.4%)	1 (3.3%)	
Censor					
Subjects Censored, n(%)	24 (100.0%)	9 (100.0%)	41 (97.6%)	29 (96.7%)	
Non-Responder: Censored at Randomization Date	15 (62.5%)	8 (88.9%)	26 (63.4%)	24 (82.8%)	
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	9 (37.5%)	1 (11.1%)	15 (36.6%)	5 (17.2%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Independent Response (Weeks)					
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	25.00 (NE, NE)	NE (13.86, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	25.00 (NE, NE)	NE (13.86, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	25.00 (NE, NE)	NE (13.86, NE)	
Min, Max	0.14, 24.71	0.14, 24.71	0.14, 25.00	0.14, 24.00	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-rbc-ti-sub.sas V.03.05 Output file: t-dur-rbc-ti-age.pdf 24AUG2023:16:31

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Table 2.8606: Analysis of Duration of RBC Transfusion Independent Response by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Subjects with Event					
Loss of RBC Transfusion Independent Response, n(%)	1 (2.0%)	1 (3.2%)	0	0	
Censor					
Subjects Censored, n(%)	48 (98.0%)	30 (96.8%)	17 (100.0%)	8 (100.0%)	
Non-Responder: Censored at Randomization Date	29 (60.4%)	24 (80.0%)	12 (70.6%)	8 (100.0%)	
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	19 (39.6%)	6 (20.0%)	5 (29.4%)	0	
Kaplan-Meier Estimate of Duration of RBC Transfusion Independent Response (Weeks)					
25-percentile (95% CI)	25.00 (NE, NE)	NE (13.86, NE)	NE (NE, NE)	NE (NE, NE)	
Median (95% CI)	25.00 (NE, NE)	NE (13.86, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	25.00 (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 25.00	0.14, 24.71	0.14, 24.71	0.14, 0.14	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-rbc-ti-sub.sas V.03.05 Output file: t-dur-rbc-ti-dipss2.pdf 24AUG2023:16:31

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Table 2.8605: Analysis of Duration of RBC Transfusion Independent Response by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Subjects with Event				
Loss of RBC Transfusion Independent Response, n(%)	0	0	1 (2.3%)	1 (4.2%)
Censor				
Subjects Censored, n(%)	5 (100.0%)	7 (100.0%)	43 (97.7%)	23 (95.8%)
Non-Responder: Censored at Randomization Date	3 (60.0%)	6 (85.7%)	26 (60.5%)	18 (78.3%)
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	2 (40.0%)	1 (14.3%)	17 (39.5%)	5 (21.7%)
Kaplan-Meier Estimate of Duration of RBC Transfusion Independent Response (Weeks)				
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	25.00 (NE, NE)	NE (13.86, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	25.00 (NE, NE)	NE (13.86, NE)
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	25.00 (NE, NE)	NE (13.86, NE)
Min, Max	0.14, 23.71	0.14, 22.29	0.14, 25.00	0.14, 24.71
Stratified Log-Rank Test p-value	NA		NA	
Adjusted Hazard Ratio (95% CI)	NA		NA	
Unstratified Log-Rank Test p-value	NA		NA	
Unadjusted Hazard Ratio (95% CI)	NA		NA	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-rbc-ti-sub.sas V.03.05 Output file: t-dur-rbc-ti-dipss3.pdf 24AUG2023:16:31

Table 2.8605: Analysis of Duration of RBC Transfusion Independent Response by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=17)	High Risk BAT (N=8)	p-value
Subjects with Event			
Loss of RBC Transfusion Independent Response, n(%)	0	0	
Censor			
Subjects Censored, n(%)	17 (100.0%)	8 (100.0%)	
Non-Responder: Censored at Randomization Date	12 (70.6%)	8 (100.0%)	
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	5 (29.4%)	0	
Kaplan-Meier Estimate of Duration of RBC Transfusion Independent Response (Weeks)			
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 24.71	0.14, 0.14	
Stratified Log-Rank Test p-value	NA		
Adjusted Hazard Ratio (95% CI)	NA		
Unstratified Log-Rank Test p-value	NA		
Unadjusted Hazard Ratio (95% CI)	NA		
P-value for interaction test			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-rbc-ti-sub.sas V.03.05 Output file: t-dur-rbc-ti-dipss3.pdf 24AUG2023:16:31

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Table 2.8604: Analysis of Duration of RBC Transfusion Independent Response by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Subjects with Event					
Loss of RBC Transfusion Independent Response, n(%)	0	0	1 (2.7%)	1 (3.1%)	
Censor					
Subjects Censored, n(%)	29 (100.0%)	7 (100.0%)	36 (97.3%)	31 (96.9%)	
Non-Responder: Censored at Randomization Date	17 (58.6%)	5 (71.4%)	24 (66.7%)	27 (87.1%)	
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	12 (41.4%)	2 (28.6%)	12 (33.3%)	4 (12.9%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Independent Response (Weeks)					
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	25.00 (NE, NE)	NE (13.86, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	25.00 (NE, NE)	NE (13.86, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	25.00 (NE, NE)	NE (13.86, NE)	
Min, Max	0.14, 24.86	0.14, 24.00	0.14, 25.00	0.14, 24.71	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-rbc-ti-sub.sas V.03.05 Output file: t-dur-rbc-ti-geo.pdf 24AUG2023:16:31

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Table 2.8607: Analysis of Duration of RBC Transfusion Independent Response by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Subjects with Event					
Loss of RBC Transfusion Independent Response, n(%)	0	0	1 (2.6%)	1 (3.0%)	
Censor					
Subjects Censored, n(%)	27 (100.0%)	6 (100.0%)	38 (97.4%)	32 (97.0%)	
Non-Responder: Censored at Randomization Date	18 (66.7%)	6 (100.0%)	23 (60.5%)	26 (81.3%)	
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	9 (33.3%)	0	15 (39.5%)	6 (18.8%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Independent Response (Weeks)					
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	25.00 (NE, NE)	NE (13.86, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	25.00 (NE, NE)	NE (13.86, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	25.00 (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 24.86	0.14, 0.14	0.14, 25.00	0.14, 24.71	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-rbc-ti-sub.sas V.03.05 Output file: t-dur-rbc-ti-hgb.pdf 24AUG2023:16:31

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Table 2.8608: Analysis of Duration of RBC Transfusion Independent Response by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=13)	BAT (N=8)	MMB (N=8)	BAT (N=8)
Subjects with Event				
Loss of RBC Transfusion Independent Response, n(%)	0	0	0	0
Censor				
Subjects Censored, n(%)	13 (100.0%)	8 (100.0%)	8 (100.0%)	8 (100.0%)
Non-Responder: Censored at Randomization Date	8 (61.5%)	6 (75.0%)	5 (62.5%)	7 (87.5%)
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	5 (38.5%)	2 (25.0%)	3 (37.5%)	1 (12.5%)
Kaplan-Meier Estimate of Duration of RBC Transfusion Independent Response (Weeks)				
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Min, Max	0.14, 24.86	0.14, 24.00	0.14, 24.00	0.14, 24.71
Stratified Log-Rank Test p-value	NA		NA	
Adjusted Hazard Ratio (95% CI)	NA		NA	
Unstratified Log-Rank Test p-value	NA		NA	
Unadjusted Hazard Ratio (95% CI)	NA		NA	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-rbc-ti-sub.sas V.03.05 Output file: t-dur-rbc-ti-mf.pdf 24AUG2023:16:31

Table 2.8608: Analysis of Duration of RBC Transfusion Independent Response by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Primary Myelofibrosis MMB (N=45)	Primary Myelofibrosis BAT (N=23)	p-value
Subjects with Event			
Loss of RBC Transfusion Independent Response, n(%)	1 (2.2%)	1 (4.3%)	
Censor			
Subjects Censored, n(%)	44 (97.8%)	22 (95.7%)	
Non-Responder: Censored at Randomization Date	28 (63.6%)	19 (86.4%)	
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	16 (36.4%)	3 (13.6%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Independent Response (Weeks)			
25-percentile (95% CI)	25.00 (NE, NE)	NE (13.86, NE)	
Median (95% CI)	25.00 (NE, NE)	NE (13.86, NE)	
75-percentile (95% CI)	25.00 (NE, NE)	NE (13.86, NE)	
Min, Max	0.14, 25.00	0.14, 24.00	
Stratified Log-Rank Test p-value	NA		
Adjusted Hazard Ratio (95% CI)	NA		
Unstratified Log-Rank Test p-value	NA		
Unadjusted Hazard Ratio (95% CI)	NA		
P-value for interaction test			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

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Table 2.8603: Analysis of Duration of RBC Transfusion Independent Response by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Subjects with Event					
Loss of RBC Transfusion Independent Response, n(%)	1 (1.9%)	1 (5.6%)	0	0	
Censor					
Subjects Censored, n(%)	51 (98.1%)	17 (94.4%)	14 (100.0%)	21 (100.0%)	
Non-Responder: Censored at Randomization Date	35 (68.6%)	15 (88.2%)	6 (42.9%)	17 (81.0%)	
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	16 (31.4%)	2 (11.8%)	8 (57.1%)	4 (19.0%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Independent Response (Weeks)					
25-percentile (95% CI)	25.00 (NE, NE)	13.86 (13.86, NE)	NE (NE, NE)	NE (NE, NE)	
Median (95% CI)	25.00 (NE, NE)	NE (13.86, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	25.00 (NE, NE)	NE (13.86, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 25.00	0.14, 22.29	0.14, 24.86	0.14, 24.71	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-rbc-ti-sub.sas V.03.05 Output file: t-dur-rbc-ti-sex.pdf 24AUG2023:16:31

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Table 2.8610: Analysis of Duration of RBC Transfusion Independent Response by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Subjects with Event					
Loss of RBC Transfusion Independent Response, n(%)	0	1 (4.2%)	1 (2.6%)	0	
Censor					
Subjects Censored, n(%)	28 (100.0%)	23 (95.8%)	37 (97.4%)	15 (100.0%)	
Non-Responder: Censored at Randomization Date	13 (46.4%)	20 (87.0%)	28 (75.7%)	12 (80.0%)	
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	15 (53.6%)	3 (13.0%)	9 (24.3%)	3 (20.0%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Independent Response (Weeks)					
25-percentile (95% CI)	NE (NE, NE)	NE (13.86, NE)	25.00 (NE, NE)	NE (NE, NE)	
Median (95% CI)	NE (NE, NE)	NE (13.86, NE)	25.00 (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (13.86, NE)	25.00 (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 24.86	0.14, 24.71	0.14, 25.00	0.14, 24.00	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-rbc-ti-sub.sas V.03.05 Output file: t-dur-rbc-ti-svb.pdf 24AUG2023:16:32

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Table 2.8611: Analysis of Duration of RBC Transfusion Independent Response
Randomized Treatment Phase
ITT-Anemic Analysis Set who are not Transfusion Independent at baseline but at any Post-baseline

	MMB (N=22)	BAT (N=3)
Subjects with Event		
Loss of RBC Transfusion Independent Response, n(%)	1 (4.5%)	1 (33.3%)
Censor		
Subjects Censored, n(%)	21 (95.5%)	2 (66.7%)
Non-Responder: Censored at Randomization Date	0	0
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	21 (100.0%)	2 (100.0%)
Kaplan-Meier Estimate of Duration of RBC Transfusion Independent Response (Weeks)		
25-percentile (95% CI)	25.00 (NE, NE)	13.86 (13.86, NE)
Median (95% CI)	25.00 (NE, NE)	NE (13.86, NE)
75-percentile (95% CI)	25.00 (NE, NE)	NE (13.86, NE)
Min, Max	13.71, 25.00	12.29, 22.29
Stratified Log-Rank Test p-value	0.008	
Adjusted Hazard Ratio (95% CI)	<0.01 (<0.01, NE)	
Unstratified Log-Rank Test p-value	0.001	
Unadjusted Hazard Ratio (95% CI)	<0.01 (<0.01, NE)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

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Table 2.8609: Analysis of Duration of RBC Transfusion Independent Response by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Subjects with Event					
Loss of RBC Transfusion Independent Response, n(%)	0	1 (5.0%)	1 (4.2%)	0	
Censor					
Subjects Censored, n(%)	42 (100.0%)	19 (95.0%)	23 (95.8%)	19 (100.0%)	
Non-Responder: Censored at Randomization Date	23 (54.8%)	16 (84.2%)	18 (78.3%)	16 (84.2%)	
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	19 (45.2%)	3 (15.8%)	5 (21.7%)	3 (15.8%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Independent Response (Weeks)					
25-percentile (95% CI)	NE (NE, NE)	NE (13.86, NE)	25.00 (NE, NE)	NE (NE, NE)	
Median (95% CI)	NE (NE, NE)	NE (13.86, NE)	25.00 (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (13.86, NE)	25.00 (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 24.86	0.14, 24.71	0.14, 25.00	0.14, 24.00	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment and baseline TD (yes,no).
Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-rbc-ti-sub.sas V.03.05 Output file: t-dur-rbc-ti-tss.pdf 24AUG2023:16:32

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Table 2.8601: Analysis of Duration of RBC Transfusion Independent Response
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Subjects with Event		
Loss of RBC Transfusion Independent Response, n(%)	1 (1.5%)	1 (2.6%)
Censor		
Subjects Censored, n(%)	65 (98.5%)	38 (97.4%)
Non-Responder: Censored at Randomization Date	41 (63.1%)	32 (84.2%)
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	24 (36.9%)	6 (15.8%)
Kaplan-Meier Estimate of Duration of RBC Transfusion Independent Response (Weeks)		
25-percentile (95% CI)	25.00 (NE, NE)	NE (13.86, NE)
Median (95% CI)	25.00 (NE, NE)	NE (13.86, NE)
75-percentile (95% CI)	25.00 (NE, NE)	NE (NE, NE)
Min, Max	0.14, 25.00	0.14, 24.71
Stratified Log-Rank Test p-value	0.008	
Adjusted Hazard Ratio (95% CI)	<0.01 (<0.01, NE)	
Unstratified Log-Rank Test p-value	0.046	
Unadjusted Hazard Ratio (95% CI)	<0.01 (<0.01, NE)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

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Table 2.3702: Analysis of Rate of New RBC Transfusion Independence by Week 24 by Age

Randomized Treatment Phase

ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	<65 Years		>=65 Years		
	MMB (N=15)	BAT (N=5)	MMB (N=37)	BAT (N=20)	p-value
RBC Transfusion Independent Rate by Week 24					
Responder, n(%)	4 (26.7%)	0	15 (40.5%)	3 (15.0%)	
95% Exact CI	0.0779, 0.5510	0.0000, 0.5218	0.2475, 0.5790	0.0321, 0.3789	
Proportion Difference - Stratified CMH Method (95% CI)	0.29 (-0.27, 0.85)		0.25 (0.01, 0.49)		
p-value	0.31		0.038		
Proportion Difference - Unstratified CMH Method (95% CI)	0.27 (-0.09, 0.63)		0.26 (0.02, 0.49)		
p-value	0.15		0.031		
Proportion Difference - Unstratified Exact Method (95% CI)	0.27 (-0.27, 0.72)		0.26 (-0.02, 0.50)		
p-value	0.53		0.073		
Unadjusted Inverse Relative Risk (95% CI)	0.30 (0.02, 4.71)		0.37 (0.12, 1.13)		
p-value [1]	0.39		0.080		
Unadjusted interaction test for Treatment*Age Group [3]					NE
Unadjusted Inverse Odds Ratio (95% CI)	0.23 (0.01, 5.12)		0.26 (0.06, 1.04)		
p-value [1]	0.36		0.057		
Unadjusted Absolute Risk Difference (95% CI)	0.20 (-0.11, 0.51)		0.26 (0.03, 0.48)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.38 (0.12, 1.14)		
p-value [2]	NE		0.083		
Adjusted interaction test for Treatment*Age Group [3]					NE
Non-Responder, n(%)	11 (73.3%)	5 (100.0%)	22 (59.5%)	17 (85.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

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Table 2.3708: Analysis of Rate of New RBC Transfusion Independence by Week 24 by Baseline MF Disease Status

Randomized Treatment Phase

ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=34)	BAT (N=16)	MMB (N=11)	BAT (N=5)
RBC Transfusion Independent Rate by Week 24				
Responder, n(%)	12 (35.3%)	2 (12.5%)	4 (36.4%)	1 (20.0%)
95% Exact CI	0.1975, 0.5351	0.0155, 0.3835	0.1093, 0.6921	0.0051, 0.7164
Proportion Difference - Stratified CMH Method (95% CI)	0.21 (-0.05, 0.47)		0.15 (-0.40, 0.69)	
p-value	0.11		0.60	
Proportion Difference - Unstratified CMH Method (95% CI)	0.23 (-0.01, 0.47)		0.16 (-0.36, 0.68)	
p-value	0.066		0.54	
Proportion Difference - Unstratified Exact Method (95% CI)	0.23 (-0.07, 0.50)		0.16 (-0.38, 0.63)	
p-value	0.18		1.00	
Unadjusted Inverse Relative Risk (95% CI)	0.35 (0.09, 1.40)		0.55 (0.08, 3.75)	
p-value [1]	0.14		0.54	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.26 (0.05, 1.35)		0.44 (0.04, 5.40)	
p-value [1]	0.11		0.52	
Unadjusted Absolute Risk Difference (95% CI)	0.23 (0.00, 0.46)		0.16 (-0.29, 0.62)	
Adjusted Inverse Relative Risk (95% CI) [2]	0.38 (0.10, 1.49)		0.58 (0.09, 3.91)	
p-value [2]	0.16		0.58	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	22 (64.7%)	14 (87.5%)	7 (63.6%)	4 (80.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.3708: Analysis of Rate of New RBC Transfusion Independence by Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	Post-PV Myelofibrosis		
	MMB (N=7)	BAT (N=4)	p-value
RBC Transfusion Independent Rate by Week 24			
Responder, n(%)	3 (42.9%)	0	
95% Exact CI	0.0990, 0.8159	0.0000, 0.6024	
Proportion Difference - Stratified CMH Method (95% CI)	0.42 (-0.26, 1.10)		
p-value	0.22		
Proportion Difference - Unstratified CMH Method (95% CI)	0.43 (-0.09, 0.95)		
p-value	0.11		
Proportion Difference - Unstratified Exact Method (95% CI)	0.43 (-0.23, 0.84)		
p-value	0.24		
Unadjusted Inverse Relative Risk (95% CI)	0.23 (0.01, 3.56)		
p-value [1]	0.29		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE
Unadjusted Inverse Odds Ratio (95% CI)	0.14 (0.01, 3.64)		
p-value [1]	0.24		
Unadjusted Absolute Risk Difference (95% CI)	0.34 (-0.10, 0.77)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE
Non-Responder, n(%)	4 (57.1%)	4 (100.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

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Table 2.3707: Analysis of Rate of New RBC Transfusion Independence by Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=25)	BAT (N=19)	p-value
RBC Transfusion Independent Rate by Week 24					
Responder, n(%)	9 (33.3%)	0	10 (40.0%)	3 (15.8%)	
95% Exact CI	0.1652, 0.5396	0.0000, 0.4593	0.2113, 0.6133	0.0338, 0.3958	
Proportion Difference - Stratified CMH Method (95% CI)	0.31 (-0.06, 0.68)		0.23 (-0.05, 0.51)		
p-value	0.096		0.11		
Proportion Difference - Unstratified CMH Method (95% CI)	0.33 (0.04, 0.62)		0.24 (-0.02, 0.51)		
p-value	0.024		0.072		
Proportion Difference - Unstratified Exact Method (95% CI)	0.33 (-0.12, 0.78)		0.24 (-0.06, 0.51)		
p-value	0.16		0.10		
Unadjusted Inverse Relative Risk (95% CI)	0.21 (0.01, 3.20)		0.39 (0.13, 1.24)		
p-value [1]	0.26		0.11		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Unadjusted Inverse Odds Ratio (95% CI)	0.15 (0.01, 2.95)		0.28 (0.06, 1.22)		
p-value [1]	0.21		0.091		
Unadjusted Absolute Risk Difference (95% CI)	0.27 (0.01, 0.53)		0.24 (-0.01, 0.49)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.41 (0.13, 1.32)		
p-value [2]	NE		0.14		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Non-Responder, n(%)	18 (66.7%)	6 (100.0%)	15 (60.0%)	16 (84.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

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Table 2.3706: Analysis of Rate of New RBC Transfusion Independence by Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	Intermediate Risk		High Risk		
	MMB (N=41)	BAT (N=18)	MMB (N=11)	BAT (N=7)	p-value
RBC Transfusion Independent Rate by Week 24					
Responder, n(%)	16 (39.0%)	3 (16.7%)	3 (27.3%)	0	
95% Exact CI	0.2420, 0.5550	0.0358, 0.4142	0.0602, 0.6097	0.0000, 0.4096	
Proportion Difference - Stratified CMH Method (95% CI)	0.19 (-0.06, 0.43)		0.26 (-0.15, 0.67)		
p-value	0.14		0.21		
Proportion Difference - Unstratified CMH Method (95% CI)	0.22 (-0.01, 0.46)		0.27 (-0.07, 0.61)		
p-value	0.066		0.12		
Proportion Difference - Unstratified Exact Method (95% CI)	0.22 (-0.05, 0.48)		0.27 (-0.19, 0.67)		
p-value	0.13		0.25		
Unadjusted Inverse Relative Risk (95% CI)	0.43 (0.14, 1.29)		0.21 (0.01, 3.61)		
p-value [1]	0.13		0.29		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NE
Unadjusted Inverse Odds Ratio (95% CI)	0.31 (0.08, 1.25)		0.16 (0.01, 3.67)		
p-value [1]	0.10		0.25		
Unadjusted Absolute Risk Difference (95% CI)	0.22 (0.00, 0.45)		0.23 (-0.08, 0.54)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.48 (0.16, 1.44)		NE		
p-value [2]	0.19		NE		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NE
Non-Responder, n(%)	25 (61.0%)	15 (83.3%)	8 (72.7%)	7 (100.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

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Table 2.3705: Analysis of Rate of New RBC Transfusion Independence by Week 24 by Baseline DIPSS Three-Level Risk

Randomized Treatment Phase

ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=3)	BAT (N=7)	MMB (N=38)	BAT (N=11)
RBC Transfusion Independent Rate by Week 24				
Responder, n(%)	0	1 (14.3%)	16 (42.1%)	2 (18.2%)
95% Exact CI	0.0000, 0.7076	0.0036, 0.5787	0.2631, 0.5918	0.0228, 0.5178
Proportion Difference - Stratified CMH Method (95% CI)	-0.33 (-1.15, 0.48)		0.22 (-0.09, 0.53)	
p-value	0.42		0.16	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.14 (-0.70, 0.41)		0.24 (-0.06, 0.54)	
p-value	0.61		0.12	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.14 (-0.71, 0.54)		0.24 (-0.10, 0.55)	
p-value	1.00		0.18	
Unadjusted Inverse Relative Risk (95% CI)	1.50 (0.08, 29.15)		0.43 (0.12, 1.60)	
p-value [1]	0.79		0.21	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	1.62 (0.05, 51.11)		0.31 (0.06, 1.61)	
p-value [1]	0.79		0.16	
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.48, 0.36)		0.24 (-0.04, 0.52)	
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.45 (0.12, 1.71)	
p-value [2]	NE		0.24	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	3 (100.0%)	6 (85.7%)	22 (57.9%)	9 (81.8%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.3705: Analysis of Rate of New RBC Transfusion Independence by Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	High Risk		
	MMB (N=11)	BAT (N=7)	p-value
RBC Transfusion Independent Rate by Week 24			
Responder, n(%)	3 (27.3%)	0	
95% Exact CI	0.0602, 0.6097	0.0000, 0.4096	
Proportion Difference - Stratified CMH Method (95% CI)	0.26 (-0.15, 0.67)		
p-value	0.21		
Proportion Difference - Unstratified CMH Method (95% CI)	0.27 (-0.07, 0.61)		
p-value	0.12		
Proportion Difference - Unstratified Exact Method (95% CI)	0.27 (-0.19, 0.67)		
p-value	0.25		
Unadjusted Inverse Relative Risk (95% CI)	0.21 (0.01, 3.61)		
p-value [1]	0.29		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NE
Unadjusted Inverse Odds Ratio (95% CI)	0.16 (0.01, 3.67)		
p-value [1]	0.25		
Unadjusted Absolute Risk Difference (95% CI)	0.23 (-0.08, 0.54)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NE
Non-Responder, n(%)	8 (72.7%)	7 (100.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

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Table 2.3704: Analysis of Rate of New RBC Transfusion Independence by Week 24 by Region

Randomized Treatment Phase

ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	North America		Europe		
	MMB (N=24)	BAT (N=5)	MMB (N=28)	BAT (N=20)	p-value
RBC Transfusion Independent Rate by Week 24					
Responder, n(%)	10 (41.7%)	0	9 (32.1%)	3 (15.0%)	
95% Exact CI	0.2211, 0.6336	0.0000, 0.5218	0.1588, 0.5235	0.0321, 0.3789	
Proportion Difference - Stratified CMH Method (95% CI)	0.42 (-0.03, 0.87)		0.15 (-0.09, 0.40)		
p-value	0.069		0.23		
Proportion Difference - Unstratified CMH Method (95% CI)	0.42 (0.08, 0.75)		0.17 (-0.07, 0.42)		
p-value	0.016		0.17		
Proportion Difference - Unstratified Exact Method (95% CI)	0.42 (-0.08, 0.85)		0.17 (-0.12, 0.44)		
p-value	0.13		0.31		
Unadjusted Inverse Relative Risk (95% CI)	0.20 (0.01, 2.93)		0.47 (0.14, 1.51)		
p-value [1]	0.24		0.20		
Unadjusted interaction test for Treatment*Region [3]					NE
Unadjusted Inverse Odds Ratio (95% CI)	0.13 (0.01, 2.53)		0.37 (0.09, 1.61)		
p-value [1]	0.18		0.19		
Unadjusted Absolute Risk Difference (95% CI)	0.34 (0.04, 0.63)		0.17 (-0.06, 0.40)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.51 (0.16, 1.61)		
p-value [2]	NE		0.25		
Adjusted interaction test for Treatment*Region [3]					NE
Non-Responder, n(%)	14 (58.3%)	5 (100.0%)	19 (67.9%)	17 (85.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

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Table 2.3703: Analysis of Rate of New RBC Transfusion Independence by Week 24 by Gender

Randomized Treatment Phase

ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	Male		Female		
	MMB (N=39)	BAT (N=13)	MMB (N=13)	BAT (N=12)	p-value
RBC Transfusion Independent Rate by Week 24					
Responder, n(%)	11 (28.2%)	2 (15.4%)	8 (61.5%)	1 (8.3%)	
95% Exact CI	0.1500, 0.4487	0.0192, 0.4545	0.3158, 0.8614	0.0021, 0.3848	
Proportion Difference - Stratified CMH Method (95% CI)	0.13 (-0.15, 0.40)		0.48 (0.15, 0.80)		
p-value	0.36		0.004		
Proportion Difference - Unstratified CMH Method (95% CI)	0.13 (-0.13, 0.39)		0.53 (0.20, 0.87)		
p-value	0.33		0.002		
Proportion Difference - Unstratified Exact Method (95% CI)	0.13 (-0.20, 0.44)		0.53 (0.16, 0.81)		
p-value	0.48		0.011		
Unadjusted Inverse Relative Risk (95% CI)	0.55 (0.14, 2.15)		0.14 (0.02, 0.93)		
p-value [1]	0.39		0.042		
Unadjusted interaction test for Treatment*Gender [3]					0.28
Unadjusted Inverse Odds Ratio (95% CI)	0.46 (0.09, 2.43)		0.06 (0.01, 0.59)		
p-value [1]	0.36		0.016		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.11, 0.37)		0.53 (0.22, 0.84)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.55 (0.14, 2.10)		0.16 (0.02, 1.06)		
p-value [2]	0.38		0.057		
Adjusted interaction test for Treatment*Gender [3]					0.30
Non-Responder, n(%)	28 (71.8%)	11 (84.6%)	5 (38.5%)	11 (91.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.3710: Analysis of Rate of New RBC Transfusion Independence by Week 24 by Baseline Spleen Volume

Randomized Treatment Phase

ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	<Median (2329.91 cm^3)		>=Median (2329.91 cm^3)		
	MMB (N=21)	BAT (N=17)	MMB (N=31)	BAT (N=8)	p-value
RBC Transfusion Independent Rate by Week 24					
Responder, n(%)	11 (52.4%)	1 (5.9%)	8 (25.8%)	2 (25.0%)	
95% Exact CI	0.2978, 0.7429	0.0015, 0.2869	0.1186, 0.4461	0.0319, 0.6509	
Proportion Difference - Stratified CMH Method (95% CI)	0.44 (0.17, 0.70)		0.00 (-0.41, 0.41)		
p-value	0.001		1.00		
Proportion Difference - Unstratified CMH Method (95% CI)	0.46 (0.21, 0.72)		0.01 (-0.36, 0.38)		
p-value	<0.001		0.97		
Proportion Difference - Unstratified Exact Method (95% CI)	0.46 (0.15, 0.71)		0.01 (-0.38, 0.39)		
p-value	0.004		1.00		
Unadjusted Inverse Relative Risk (95% CI)	0.11 (0.02, 0.79)		0.97 (0.25, 3.70)		
p-value [1]	0.028		0.96		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.17
Unadjusted Inverse Odds Ratio (95% CI)	0.06 (0.01, 0.51)		0.96 (0.16, 5.75)		
p-value [1]	0.010		0.96		
Unadjusted Absolute Risk Difference (95% CI)	0.46 (0.22, 0.71)		0.01 (-0.33, 0.35)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.12 (0.02, 0.86)		1.00 (0.25, 3.98)		
p-value [2]	0.035		1.00		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.16
Non-Responder, n(%)	10 (47.6%)	16 (94.1%)	23 (74.2%)	6 (75.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.3709: Analysis of Rate of New RBC Transfusion Independence by Week 24 by Baseline TSS

Randomized Treatment Phase

ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	<18		>=18		
	MMB (N=35)	BAT (N=14)	MMB (N=17)	BAT (N=11)	p-value
RBC Transfusion Independent Rate by Week 24					
Responder, n(%)	15 (42.9%)	2 (14.3%)	4 (23.5%)	1 (9.1%)	
95% Exact CI	0.2632, 0.6065	0.0178, 0.4281	0.0681, 0.4990	0.0023, 0.4128	
Proportion Difference - Stratified CMH Method (95% CI)	0.29 (0.02, 0.55)		0.14 (-0.15, 0.44)		
p-value	0.033		0.34		
Proportion Difference - Unstratified CMH Method (95% CI)	0.29 (0.02, 0.55)		0.14 (-0.15, 0.44)		
p-value	0.033		0.34		
Proportion Difference - Unstratified Exact Method (95% CI)	0.29 (-0.03, 0.58)		0.14 (-0.23, 0.49)		
p-value	0.096		0.62		
Unadjusted Inverse Relative Risk (95% CI)	0.33 (0.09, 1.27)		0.39 (0.05, 3.02)		
p-value [1]	0.11		0.36		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.91
Unadjusted Inverse Odds Ratio (95% CI)	0.22 (0.04, 1.15)		0.33 (0.03, 3.38)		
p-value [1]	0.072		0.35		
Unadjusted Absolute Risk Difference (95% CI)	0.29 (0.04, 0.53)		0.14 (-0.12, 0.41)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	20 (57.1%)	12 (85.7%)	13 (76.5%)	10 (90.9%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk is not applicable for this analysis, since the stratification variables are already included in variables used in the subset and the subgroup.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.3701: Analysis of Rate of New RBC Transfusion Independence by Week 24

Randomized Treatment Phase

ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	MMB (N=52)	BAT (N=25)	Total (N=77)
RBC Transfusion Independent Rate by Week 24			
Responder, n(%)	19 (36.5%)	3 (12.0%)	22 (28.6%)
95% Exact CI	0.2362, 0.5104	0.0255, 0.3122	0.1885, 0.4000
Proportion Difference - Stratified CMH Method (95% CI)	0.23 (0.03, 0.43)		
p-value	0.022		
Proportion Difference - Unstratified CMH Method (95% CI)	0.25 (0.06, 0.44)		
p-value	0.011		
Proportion Difference - Unstratified Exact Method (95% CI)	0.25 (0.01, 0.46)		
p-value	0.032		
Unadjusted Inverse Relative Risk (95% CI)	0.33 (0.11, 1.01)		
p-value [1]	0.051		
Unadjusted Inverse Odds Ratio (95% CI)	0.24 (0.06, 0.90)		
p-value [1]	0.034		
Unadjusted Absolute Risk Difference (95% CI)	0.25 (0.06, 0.43)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.35 (0.11, 1.07)		
p-value [2]	0.065		
Non-Responder, n(%)	33 (63.5%)	22 (88.0%)	55 (71.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel.

RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.3402: Analysis of RBC Transfusion Independent Response Rate at Week 24 and at Week 12

Randomized Treatment Phase

ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
All Strata Combined			
RBC Transfusion Independent Rate at Week 24			
Responder, n(%)	20 (32.8%)	1 (3.3%)	21 (23.1%)
95% Exact CI	0.2131, 0.4600	0.0008, 0.1722	0.1489, 0.3309
Proportion Difference - Stratified CMH Method (95% CI)	0.27 (0.12, 0.43)		
p-value	<0.001		
Proportion Difference - Unstratified CMH Method (95% CI)	0.29 (0.15, 0.44)		
p-value	<0.001		
Proportion Difference - Unstratified Exact Method (95% CI)	0.29 (0.08, 0.49)		
p-value	0.001		
Unadjusted Inverse Relative Risk (95% CI)	0.10 (0.01, 0.72)		
p-value [1]	0.022		
Unadjusted Inverse Odds Ratio (95% CI)	0.07 (0.01, 0.56)		
p-value [1]	0.012		
Unadjusted Absolute Risk Difference (95% CI)	0.29 (0.16, 0.43)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Non-Responder, n(%)	41 (67.2%)	29 (96.7%)	70 (76.9%)
Transfusion (except bleeding) in the last 12 weeks	26 (42.6%)	23 (76.7%)	49 (53.8%)
Any Hgb assessment < 8g/dL in the last 12 weeks	21 (34.4%)	15 (50.0%)	36 (39.6%)
Last Participation date < Day 162 in RT phase	15 (24.6%)	5 (16.7%)	20 (22.0%)
Other	9 (14.8%)	3 (10.0%)	12 (13.2%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

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Table 2.3402: Analysis of RBC Transfusion Independent Response Rate at Week 24 and at Week 12

Randomized Treatment Phase

ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
RBC Transfusion Independent Rate at Week 12			
Responder, n(%)	12 (19.7%)	0	12 (13.2%)
95% Exact CI	0.1060, 0.3184	0.0000, 0.1157	0.0700, 0.2190
Proportion Difference - Stratified CMH Method (95% CI)	0.19 (0.05, 0.33)		
p-value	0.008		
Proportion Difference - Unstratified CMH Method (95% CI)	0.20 (0.09, 0.31)		
p-value	<0.001		
Proportion Difference - Unstratified Exact Method (95% CI)	0.20 (-0.02, 0.40)		
p-value	0.007		
Unadjusted Inverse Relative Risk (95% CI)	0.08 (0.00, 1.31)		
p-value [1]	0.076		
Unadjusted Inverse Odds Ratio (95% CI)	0.06 (0.00, 1.14)		
p-value [1]	0.061		
Unadjusted Absolute Risk Difference (95% CI)	0.19 (0.08, 0.29)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Non-Responder, n(%)	49 (80.3%)	30 (100.0%)	79 (86.8%)
Transfusion (except bleeding) in the last 12 weeks	41 (67.2%)	25 (83.3%)	66 (72.5%)
Any Hgb assessment < 8g/dL in the last 12 weeks	35 (57.4%)	18 (60.0%)	53 (58.2%)
Last Participation date < Day 78 in RT phase	6 (9.8%)	4 (13.3%)	10 (11.0%)
Other	20 (32.8%)	5 (16.7%)	25 (27.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

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Table 2.3402: Analysis of RBC Transfusion Independent Response Rate at Week 24 and at Week 12

Randomized Treatment Phase

ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
Stratum 1			
Transfusion Dependence Yes and Baseline TSS <18	35	14	49
RBC Transfusion Independent Rate at Week 24			
Responder, n(%)	14 (40.0%)	0	14 (28.6%)
95% Exact CI	0.2387, 0.5789	0.0000, 0.2316	0.1658, 0.4326
Proportion Difference (95% CI)	0.40 (0.21, 0.59)		
Proportion Difference using Exact Method (95% CI)	0.40 (0.09, 0.67)		
Non-Responder, n(%)	21 (60.0%)	14 (100.0%)	35 (71.4%)
Transfusion (except bleeding) in the last 12 weeks	15 (42.9%)	11 (78.6%)	26 (53.1%)
Any Hgb assessment < 8g/dL in the last 12 weeks	12 (34.3%)	6 (42.9%)	18 (36.7%)
Last Participation date < Day 162 in RT phase	6 (17.1%)	2 (14.3%)	8 (16.3%)
Other	7 (20.0%)	2 (14.3%)	9 (18.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Table 2.3402: Analysis of RBC Transfusion Independent Response Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
RBC Transfusion Independent Rate at Week 12			
Responder, n(%)	7 (20.0%)	0	7 (14.3%)
95% Exact CI	0.0844, 0.3694	0.0000, 0.2316	0.0594, 0.2724
Proportion Difference (95% CI)	0.20 (0.03, 0.37)		
Proportion Difference using Exact Method (95% CI)	0.20 (-0.12, 0.49)		
Non-Responder, n(%)	28 (80.0%)	14 (100.0%)	42 (85.7%)
Transfusion (except bleeding) in the last 12 weeks	25 (71.4%)	12 (85.7%)	37 (75.5%)
Any Hgb assessment < 8g/dL in the last 12 weeks	22 (62.9%)	9 (64.3%)	31 (63.3%)
Last Participation date < Day 78 in RT phase	1 (2.9%)	2 (14.3%)	3 (6.1%)
Other	13 (37.1%)	3 (21.4%)	16 (32.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.3402: Analysis of RBC Transfusion Independent Response Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
Stratum 2			
Transfusion Dependence Yes and Baseline TSS >=18	17	11	28
RBC Transfusion Independent Rate at Week 24			
Responder, n(%)	3 (17.6%)	1 (9.1%)	4 (14.3%)
95% Exact CI	0.0380, 0.4343	0.0023, 0.4128	0.0403, 0.3267
Proportion Difference (95% CI)	0.09 (-0.20, 0.37)		
Proportion Difference using Exact Method (95% CI)	0.09 (-0.28, 0.44)		
Non-Responder, n(%)	14 (82.4%)	10 (90.9%)	24 (85.7%)
Transfusion (except bleeding) in the last 12 weeks	8 (47.1%)	8 (72.7%)	16 (57.1%)
Any Hgb assessment < 8g/dL in the last 12 weeks	7 (41.2%)	7 (63.6%)	14 (50.0%)
Last Participation date < Day 162 in RT phase	6 (35.3%)	2 (18.2%)	8 (28.6%)
Other	2 (11.8%)	1 (9.1%)	3 (10.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Table 2.3402: Analysis of RBC Transfusion Independent Response Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
RBC Transfusion Independent Rate at Week 12			
Responder, n(%)	3 (17.6%)	0	3 (10.7%)
95% Exact CI	0.0380, 0.4343	0.0000, 0.2849	0.0227, 0.2823
Proportion Difference (95% CI)	0.18 (-0.05, 0.41)		
Proportion Difference using Exact Method (95% CI)	0.18 (-0.20, 0.52)		
Non-Responder, n(%)	14 (82.4%)	11 (100.0%)	25 (89.3%)
Transfusion (except bleeding) in the last 12 weeks	11 (64.7%)	9 (81.8%)	20 (71.4%)
Any Hgb assessment < 8g/dL in the last 12 weeks	11 (64.7%)	8 (72.7%)	19 (67.9%)
Last Participation date < Day 78 in RT phase	3 (17.6%)	2 (18.2%)	5 (17.9%)
Other	7 (41.2%)	1 (9.1%)	8 (28.6%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Table 2.3402: Analysis of RBC Transfusion Independent Response Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
Stratum 3			
Transfusion Dependence No and Baseline TSS <18	5	2	7
RBC Transfusion Independent Rate at Week 24			
Responder, n(%)	3 (60.0%)	0	3 (42.9%)
95% Exact CI	0.1466, 0.9473	0.0000, 0.8419	0.0990, 0.8159
Proportion Difference (95% CI)	0.60 (-0.28, 1.48)		
Proportion Difference using Exact Method (95% CI)	0.60 (-0.32, 0.99)		
Non-Responder, n(%)	2 (40.0%)	2 (100.0%)	4 (57.1%)
Transfusion (except bleeding) in the last 12 weeks	0	1 (50.0%)	1 (14.3%)
Any Hgb assessment < 8g/dL in the last 12 weeks	0	1 (50.0%)	1 (14.3%)
Last Participation date < Day 162 in RT phase	2 (40.0%)	1 (50.0%)	3 (42.9%)
Other	0	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.3402: Analysis of RBC Transfusion Independent Response Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
RBC Transfusion Independent Rate at Week 12			
Responder, n(%)	2 (40.0%)	0	2 (28.6%)
95% Exact CI	0.0527, 0.8534	0.0000, 0.8419	0.0367, 0.7096
Proportion Difference (95% CI)	0.40 (-0.48, 1.28)		
Proportion Difference using Exact Method (95% CI)	0.40 (-0.49, 0.90)		
Non-Responder, n(%)	3 (60.0%)	2 (100.0%)	5 (71.4%)
Transfusion (except bleeding) in the last 12 weeks	2 (40.0%)	1 (50.0%)	3 (42.9%)
Any Hgb assessment < 8g/dL in the last 12 weeks	1 (20.0%)	0	1 (14.3%)
Last Participation date < Day 78 in RT phase	1 (20.0%)	0	1 (14.3%)
Other	0	1 (50.0%)	1 (14.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Table 2.3402: Analysis of RBC Transfusion Independent Response Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
Stratum 4			
Transfusion Dependence No and Baseline TSS >=18	4	3	7
RBC Transfusion Independent Rate at Week 24			
Responder, n(%)	0	0	0
95% Exact CI	0.0000, 0.6024	0.0000, 0.7076	0.0000, 0.4096
Proportion Difference (95% CI)	0.00 (-0.57, 0.57)		
Proportion Difference using Exact Method(95% CI)	NA		
Non-Responder, n(%)	4 (100.0%)	3 (100.0%)	7 (100.0%)
Transfusion (except bleeding) in the last 12 weeks	3 (75.0%)	3 (100.0%)	6 (85.7%)
Any Hgb assessment < 8g/dL in the last 12 weeks	2 (50.0%)	1 (33.3%)	3 (42.9%)
Last Participation date < Day 162 in RT phase	1 (25.0%)	0	1 (14.3%)
Other	0	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

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Table 2.3402: Analysis of RBC Transfusion Independent Response Rate at Week 24 and at Week 12

Randomized Treatment Phase

ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
RBC Transfusion Independent Rate at Week 12			
Responder, n(%)	0	0	0
95% Exact CI	0.0000, 0.6024	0.0000, 0.7076	0.0000, 0.4096
Proportion Difference (95% CI)	0.00 (-0.57, 0.57)		
Proportion Difference using Exact Method (95% CI)	NA		
Non-Responder, n(%)	4 (100.0%)	3 (100.0%)	7 (100.0%)
Transfusion (except bleeding) in the last 12 weeks	3 (75.0%)	3 (100.0%)	6 (85.7%)
Any Hgb assessment < 8g/dL in the last 12 weeks	1 (25.0%)	1 (33.3%)	2 (28.6%)
Last Participation date < Day 78 in RT phase	1 (25.0%)	0	1 (14.3%)
Other	0	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

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Table 2.3401: Analysis of RBC Transfusion Independent Response Rate at Week 24 and at Week 12

Randomized Treatment Phase

ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=5)	BAT (N=9)	Total (N=14)
All Strata Combined			
RBC Transfusion Independent Rate at Week 24			
Responder, n(%)	2 (40.0%)	4 (44.4%)	6 (42.9%)
95% Exact CI	0.0527, 0.8534	0.1370, 0.7880	0.1766, 0.7114
Proportion Difference - Stratified CMH Method (95% CI)	-0.04 (-0.71, 0.64)		
p-value	0.91		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.04 (-0.64, 0.55)		
p-value	0.88		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.04 (-0.55, 0.50)		
p-value	1.00		
Unadjusted Inverse Relative Risk (95% CI)	1.11 (0.30, 4.07)		
p-value [1]	0.87		
Unadjusted Inverse Odds Ratio (95% CI)	1.20 (0.13, 11.05)		
p-value [1]	0.87		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.58, 0.49)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.10 (0.30, 3.97)		
p-value [2]	0.89		
Non-Responder, n(%)	3 (60.0%)	5 (55.6%)	8 (57.1%)
Transfusion (except bleeding) in the last 12 weeks	0	2 (22.2%)	2 (14.3%)
Any Hgb assessment < 8g/dL in the last 12 weeks	0	3 (33.3%)	3 (21.4%)
Last Participation date < Day 162 in RT phase	3 (60.0%)	2 (22.2%)	5 (35.7%)
Other	0	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

Table 2.3401: Analysis of RBC Transfusion Independent Response Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=5)	BAT (N=9)	Total (N=14)
RBC Transfusion Independent Rate at Week 12			
Responder, n(%)	3 (60.0%)	3 (33.3%)	6 (42.9%)
95% Exact CI	0.1466, 0.9473	0.0749, 0.7007	0.1766, 0.7114
Proportion Difference - Stratified CMH Method (95% CI)		0.26 (-0.41, 0.93)	
p-value	0.45		
Proportion Difference - Unstratified CMH Method (95% CI)		0.27 (-0.32, 0.85)	
p-value	0.37		
Proportion Difference - Unstratified Exact Method (95% CI)		0.27 (-0.30, 0.72)	
p-value	0.58		
Unadjusted Inverse Relative Risk (95% CI)		0.56 (0.17, 1.79)	
p-value [1]	0.32		
Unadjusted Inverse Odds Ratio (95% CI)		0.33 (0.03, 3.20)	
p-value [1]	0.34		
Unadjusted Absolute Risk Difference (95% CI)		0.27 (-0.26, 0.80)	
Adjusted Inverse Relative Risk (95% CI) [2]		0.56 (0.18, 1.80)	
p-value [2]	0.33		
Non-Responder, n(%)	2 (40.0%)	6 (66.7%)	8 (57.1%)
Transfusion (except bleeding) in the last 12 weeks	1 (20.0%)	3 (33.3%)	4 (28.6%)
Any Hgb assessment < 8g/dL in the last 12 weeks	1 (20.0%)	2 (22.2%)	3 (21.4%)
Last Participation date < Day 78 in RT phase	1 (20.0%)	2 (22.2%)	3 (21.4%)
Other	0	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline TSS (<18, >=18) as covariates.

Table 2.3401: Analysis of RBC Transfusion Independent Response Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=5)	BAT (N=9)	Total (N=14)
Stratum 3			
Transfusion Dependence No and Baseline TSS <18	2	4	6
RBC Transfusion Independent Rate at Week 24			
Responder, n(%)	1 (50.0%)	2 (50.0%)	3 (50.0%)
95% Exact CI	0.0126, 0.9874	0.0676, 0.9324	0.1181, 0.8819
Proportion Difference (95% CI)	0.00 (-1.13, 1.13)		
Proportion Difference using Exact Method (95% CI)	0.00 (-0.84, 0.84)		
Non-Responder, n(%)	1 (50.0%)	2 (50.0%)	3 (50.0%)
Transfusion (except bleeding) in the last 12 weeks	0	1 (25.0%)	1 (16.7%)
Any Hgb assessment < 8g/dL in the last 12 weeks	0	2 (50.0%)	2 (33.3%)
Last Participation date < Day 162 in RT phase	1 (50.0%)	0	1 (16.7%)
Other	0	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

Table 2.3401: Analysis of RBC Transfusion Independent Response Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=5)	BAT (N=9)	Total (N=14)
RBC Transfusion Independent Rate at Week 12			
Responder, n(%)	1 (50.0%)	1 (25.0%)	2 (33.3%)
95% Exact CI	0.0126, 0.9874	0.0063, 0.8059	0.0433, 0.7772
Proportion Difference (95% CI)	0.25 (-0.86, 1.36)		
Proportion Difference using Exact Method (95% CI)	0.25 (-0.64, 0.89)		
Non-Responder, n(%)	1 (50.0%)	3 (75.0%)	4 (66.7%)
Transfusion (except bleeding) in the last 12 weeks	0	2 (50.0%)	2 (33.3%)
Any Hgb assessment < 8g/dL in the last 12 weeks	0	2 (50.0%)	2 (33.3%)
Last Participation date < Day 78 in RT phase	1 (50.0%)	0	1 (16.7%)
Other	0	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline TSS (<18, >=18) as covariates.

Table 2.3401: Analysis of RBC Transfusion Independent Response Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=5)	BAT (N=9)	Total (N=14)
Stratum 4			
Transfusion Dependence No and Baseline TSS >=18	3	5	8
RBC Transfusion Independent Rate at Week 24			
Responder, n(%)	1 (33.3%)	2 (40.0%)	3 (37.5%)
95% Exact CI	0.0084, 0.9057	0.0527, 0.8534	0.0852, 0.7551
Proportion Difference (95% CI)	-0.07 (-0.89, 0.76)		
Proportion Difference using Exact Method (95% CI)	-0.07 (-0.71, 0.63)		
Non-Responder, n(%)	2 (66.7%)	3 (60.0%)	5 (62.5%)
Transfusion (except bleeding) in the last 12 weeks	0	1 (20.0%)	1 (12.5%)
Any Hgb assessment < 8g/dL in the last 12 weeks	0	1 (20.0%)	1 (12.5%)
Last Participation date < Day 162 in RT phase	2 (66.7%)	2 (40.0%)	4 (50.0%)
Other	0	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

Table 2.3401: Analysis of RBC Transfusion Independent Response Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=5)	BAT (N=9)	Total (N=14)
RBC Transfusion Independent Rate at Week 12			
Responder, n(%)	2 (66.7%)	2 (40.0%)	4 (50.0%)
95% Exact CI	0.0943, 0.9916	0.0527, 0.8534	0.1570, 0.8430
Proportion Difference (95% CI)	0.27 (-0.56, 1.09)		
Proportion Difference using Exact Method (95% CI)	0.27 (-0.48, 0.82)		
Non-Responder, n(%)	1 (33.3%)	3 (60.0%)	4 (50.0%)
Transfusion (except bleeding) in the last 12 weeks	1 (33.3%)	1 (20.0%)	2 (25.0%)
Any Hgb assessment < 8g/dL in the last 12 weeks	1 (33.3%)	0	1 (12.5%)
Last Participation date < Day 78 in RT phase	0	2 (40.0%)	2 (25.0%)
Other	0	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.3102: Analysis of Rate of RBC Transfusion Independence by Week 24 by Age

Randomized Treatment Phase

ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
RBC Transfusion Independent Rate by Week 24					
Responder, n(%)	9 (37.5%)	1 (11.1%)	16 (38.1%)	6 (20.0%)	
95% Exact CI	0.1880, 0.5941	0.0028, 0.4825	0.2357, 0.5436	0.0771, 0.3857	
Proportion Difference - Stratified CMH Method (95% CI)	0.25 (-0.12, 0.62)		0.18 (-0.04, 0.40)		
p-value	0.19		0.11		
Proportion Difference - Unstratified CMH Method (95% CI)	0.26 (-0.05, 0.58)		0.18 (-0.03, 0.39)		
p-value	0.10		0.091		
Proportion Difference - Unstratified Exact Method (95% CI)	0.26 (-0.12, 0.61)		0.18 (-0.06, 0.40)		
p-value	0.22		0.12		
Unadjusted Inverse Relative Risk (95% CI)	0.30 (0.04, 2.02)		0.53 (0.23, 1.18)		
p-value [1]	0.21		0.12		
Unadjusted interaction test for Treatment*Age Group [3]					0.54
Unadjusted Inverse Odds Ratio (95% CI)	0.21 (0.02, 1.95)		0.41 (0.14, 1.21)		
p-value [1]	0.17		0.11		
Unadjusted Absolute Risk Difference (95% CI)	0.26 (-0.02, 0.55)		0.18 (-0.02, 0.39)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.32 (0.06, 1.71)		0.52 (0.24, 1.17)		
p-value [2]	0.18		0.11		
Adjusted interaction test for Treatment*Age Group [3]					0.70
Non-Responder, n(%)	15 (62.5%)	8 (88.9%)	26 (61.9%)	24 (80.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.3108: Analysis of Rate of RBC Transfusion Independence by Week 24 by Baseline MF Disease Status

Randomized Treatment Phase

ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
RBC Transfusion Independent Rate by Week 24				
Responder, n(%)	17 (37.8%)	4 (17.4%)	5 (38.5%)	2 (25.0%)
95% Exact CI	0.2377, 0.5346	0.0495, 0.3878	0.1386, 0.6842	0.0319, 0.6509
Proportion Difference - Stratified CMH Method (95% CI)	0.20 (-0.04, 0.43)		0.06 (-0.38, 0.50)	
p-value	0.11		0.80	
Proportion Difference - Unstratified CMH Method (95% CI)	0.20 (-0.01, 0.42)		0.13 (-0.30, 0.57)	
p-value	0.066		0.54	
Proportion Difference - Unstratified Exact Method (95% CI)	0.20 (-0.05, 0.43)		0.13 (-0.31, 0.53)	
p-value	0.10		0.66	
Unadjusted Inverse Relative Risk (95% CI)	0.46 (0.18, 1.21)		0.65 (0.16, 2.59)	
p-value [1]	0.12		0.54	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.35 (0.10, 1.19)		0.53 (0.08, 3.76)	
p-value [1]	0.093		0.53	
Unadjusted Absolute Risk Difference (95% CI)	0.20 (-0.01, 0.41)		0.13 (-0.27, 0.53)	
Adjusted Inverse Relative Risk (95% CI) [2]	0.47 (0.18, 1.22)		0.82 (0.20, 3.40)	
p-value [2]	0.12		0.78	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	28 (62.2%)	19 (82.6%)	8 (61.5%)	6 (75.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.3108: Analysis of Rate of RBC Transfusion Independence by Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
RBC Transfusion Independent Rate by Week 24			
Responder, n(%)	3 (37.5%)	1 (12.5%)	
95% Exact CI	0.0852, 0.7551	0.0032, 0.5265	
Proportion Difference - Stratified CMH Method (95% CI)	0.35 (-0.21, 0.92)		
p-value	0.22		
Proportion Difference - Unstratified CMH Method (95% CI)	0.25 (-0.20, 0.70)		
p-value	0.28		
Proportion Difference - Unstratified Exact Method (95% CI)	0.25 (-0.29, 0.70)		
p-value	0.57		
Unadjusted Inverse Relative Risk (95% CI)	0.33 (0.04, 2.56)		
p-value [1]	0.29		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.86
Unadjusted Inverse Odds Ratio (95% CI)	0.24 (0.02, 3.01)		
p-value [1]	0.27		
Unadjusted Absolute Risk Difference (95% CI)	0.25 (-0.16, 0.66)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.67
Non-Responder, n(%)	5 (62.5%)	7 (87.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

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Table 2.3107: Analysis of Rate of RBC Transfusion Independence by Week 24 by Baseline Hemoglobin Level

Randomized Treatment Phase

ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
RBC Transfusion Independent Rate by Week 24					
Responder, n(%)	9 (33.3%)	0	16 (41.0%)	7 (21.2%)	
95% Exact CI	0.1652, 0.5396	0.0000, 0.4593	0.2557, 0.5790	0.0898, 0.3891	
Proportion Difference - Stratified CMH Method (95% CI)	0.31 (-0.06, 0.68)		0.19 (-0.04, 0.42)		
p-value	0.096		0.10		
Proportion Difference - Unstratified CMH Method (95% CI)	0.33 (0.04, 0.62)		0.20 (-0.01, 0.41)		
p-value	0.024		0.068		
Proportion Difference - Unstratified Exact Method (95% CI)	0.33 (-0.12, 0.78)		0.20 (-0.03, 0.42)		
p-value	0.16		0.083		
Unadjusted Inverse Relative Risk (95% CI)	0.21 (0.01, 3.20)		0.52 (0.24, 1.10)		
p-value [1]	0.26		0.088		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Unadjusted Inverse Odds Ratio (95% CI)	0.15 (0.01, 2.95)		0.39 (0.14, 1.11)		
p-value [1]	0.21		0.077		
Unadjusted Absolute Risk Difference (95% CI)	0.27 (0.01, 0.53)		0.20 (-0.01, 0.41)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.53 (0.25, 1.13)		
p-value [2]	NE		0.10		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Non-Responder, n(%)	18 (66.7%)	6 (100.0%)	23 (59.0%)	26 (78.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

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Table 2.3106: Analysis of Rate of RBC Transfusion Independence by Week 24 by Baseline DIPSS Two-Level Risk

Randomized Treatment Phase

ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
RBC Transfusion Independent Rate by Week 24					
Responder, n(%)	20 (40.8%)	7 (22.6%)	5 (29.4%)	0	
95% Exact CI	0.2700, 0.5579	0.0959, 0.4110	0.1031, 0.5596	0.0000, 0.3694	
Proportion Difference - Stratified CMH Method (95% CI)	0.19 (-0.04, 0.41)		0.27 (-0.07, 0.62)		
p-value	0.10		0.12		
Proportion Difference - Unstratified CMH Method (95% CI)	0.18 (-0.02, 0.39)		0.29 (0.01, 0.58)		
p-value	0.082		0.041		
Proportion Difference - Unstratified Exact Method (95% CI)	0.18 (-0.04, 0.40)		0.29 (-0.11, 0.65)		
p-value	0.14		0.14		
Unadjusted Inverse Relative Risk (95% CI)	0.55 (0.27, 1.15)		0.18 (0.01, 2.94)		
p-value [1]	0.11		0.23		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NE
Unadjusted Inverse Odds Ratio (95% CI)	0.42 (0.15, 1.17)		0.13 (0.01, 2.75)		
p-value [1]	0.097		0.19		
Unadjusted Absolute Risk Difference (95% CI)	0.18 (-0.02, 0.38)		0.25 (-0.01, 0.51)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.54 (0.26, 1.13)		NE		
p-value [2]	0.10		NE		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NE
Non-Responder, n(%)	29 (59.2%)	24 (77.4%)	12 (70.6%)	8 (100.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

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Table 2.3105: Analysis of Rate of RBC Transfusion Independence by Week 24 by Baseline DIPSS Three-Level Risk

Randomized Treatment Phase

ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
RBC Transfusion Independent Rate by Week 24				
Responder, n(%)	2 (40.0%)	1 (14.3%)	18 (40.9%)	6 (25.0%)
95% Exact CI	0.0527, 0.8534	0.0036, 0.5787	0.2634, 0.5675	0.0977, 0.4671
Proportion Difference - Stratified CMH Method (95% CI)	-0.33 (-1.15, 0.48)		0.16 (-0.11, 0.42)	
p-value	0.42		0.25	
Proportion Difference - Unstratified CMH Method (95% CI)	0.26 (-0.32, 0.83)		0.16 (-0.07, 0.39)	
p-value	0.38		0.18	
Proportion Difference - Unstratified Exact Method (95% CI)	0.26 (-0.32, 0.74)		0.16 (-0.09, 0.40)	
p-value	0.52		0.29	
Unadjusted Inverse Relative Risk (95% CI)	0.36 (0.04, 2.94)		0.61 (0.28, 1.33)	
p-value [1]	0.34		0.22	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.25 (0.02, 4.00)		0.48 (0.16, 1.45)	
p-value [1]	0.33		0.19	
Unadjusted Absolute Risk Difference (95% CI)	0.26 (-0.24, 0.76)		0.16 (-0.07, 0.39)	
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.62 (0.28, 1.37)	
p-value [2]	NE		0.24	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	3 (60.0%)	6 (85.7%)	26 (59.1%)	18 (75.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.3105: Analysis of Rate of RBC Transfusion Independence by Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
RBC Transfusion Independent Rate by Week 24			
Responder, n(%)	5 (29.4%)	0	
95% Exact CI	0.1031, 0.5596	0.0000, 0.3694	
Proportion Difference - Stratified CMH Method (95% CI)	0.27 (-0.07, 0.62)		
p-value	0.12		
Proportion Difference - Unstratified CMH Method (95% CI)	0.29 (0.01, 0.58)		
p-value	0.041		
Proportion Difference - Unstratified Exact Method (95% CI)	0.29 (-0.11, 0.65)		
p-value	0.14		
Unadjusted Inverse Relative Risk (95% CI)	0.18 (0.01, 2.94)		
p-value [1]	0.23		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NE
Unadjusted Inverse Odds Ratio (95% CI)	0.13 (0.01, 2.75)		
p-value [1]	0.19		
Unadjusted Absolute Risk Difference (95% CI)	0.25 (-0.01, 0.51)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NE
Non-Responder, n(%)	12 (70.6%)	8 (100.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

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Table 2.3104: Analysis of Rate of RBC Transfusion Independence by Week 24 by Region

Randomized Treatment Phase

ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
RBC Transfusion Independent Rate by Week 24					
Responder, n(%)	12 (41.4%)	2 (28.6%)	13 (35.1%)	5 (15.6%)	
95% Exact CI	0.2352, 0.6106	0.0367, 0.7096	0.2021, 0.5254	0.0528, 0.3279	
Proportion Difference - Stratified CMH Method (95% CI)	0.17 (-0.24, 0.59)		0.18 (-0.03, 0.40)		
p-value	0.41		0.095		
Proportion Difference - Unstratified CMH Method (95% CI)	0.13 (-0.29, 0.54)		0.20 (-0.01, 0.40)		
p-value	0.54		0.061		
Proportion Difference - Unstratified Exact Method (95% CI)	0.13 (-0.29, 0.52)		0.20 (-0.04, 0.42)		
p-value	0.68		0.099		
Unadjusted Inverse Relative Risk (95% CI)	0.69 (0.20, 2.41)		0.44 (0.18, 1.11)		
p-value [1]	0.56		0.083		
Unadjusted interaction test for Treatment*Region [3]					0.61
Unadjusted Inverse Odds Ratio (95% CI)	0.57 (0.09, 3.42)		0.34 (0.11, 1.10)		
p-value [1]	0.54		0.072		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.25, 0.51)		0.20 (0.00, 0.39)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.61 (0.22, 1.68)		0.46 (0.19, 1.14)		
p-value [2]	0.34		0.093		
Adjusted interaction test for Treatment*Region [3]					0.52
Non-Responder, n(%)	17 (58.6%)	5 (71.4%)	24 (64.9%)	27 (84.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.3103: Analysis of Rate of RBC Transfusion Independence by Week 24 by Gender

Randomized Treatment Phase

ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
RBC Transfusion Independent Rate by Week 24					
Responder, n(%)	17 (32.7%)	3 (16.7%)	8 (57.1%)	4 (19.0%)	
95% Exact CI	0.2033, 0.4711	0.0358, 0.4142	0.2886, 0.8234	0.0545, 0.4191	
Proportion Difference - Stratified CMH Method (95% CI)	0.15 (-0.10, 0.41)		0.37 (0.09, 0.65)		
p-value	0.24		0.011		
Proportion Difference - Unstratified CMH Method (95% CI)	0.16 (-0.06, 0.39)		0.38 (0.06, 0.70)		
p-value	0.16		0.020		
Proportion Difference - Unstratified Exact Method (95% CI)	0.16 (-0.11, 0.42)		0.38 (0.03, 0.67)		
p-value	0.24		0.031		
Unadjusted Inverse Relative Risk (95% CI)	0.51 (0.17, 1.54)		0.33 (0.12, 0.90)		
p-value [1]	0.23		0.030		
Unadjusted interaction test for Treatment*Gender [3]					0.59
Unadjusted Inverse Odds Ratio (95% CI)	0.41 (0.10, 1.62)		0.18 (0.04, 0.81)		
p-value [1]	0.20		0.025		
Unadjusted Absolute Risk Difference (95% CI)	0.16 (-0.05, 0.37)		0.38 (0.07, 0.69)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.52 (0.18, 1.52)		0.32 (0.10, 0.97)		
p-value [2]	0.23		0.044		
Adjusted interaction test for Treatment*Gender [3]					0.45
Non-Responder, n(%)	35 (67.3%)	15 (83.3%)	6 (42.9%)	17 (81.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.3110: Analysis of Rate of RBC Transfusion Independence by Week 24 by Baseline Spleen Volume

Randomized Treatment Phase

ITT-Anemic Analysis Set

	<Median (2329.91 cm^3)		>=Median (2329.91 cm^3)		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
RBC Transfusion Independent Rate by Week 24					
Responder, n(%)	15 (53.6%)	4 (16.7%)	10 (26.3%)	3 (20.0%)	
95% Exact CI	0.3387, 0.7249	0.0474, 0.3738	0.1340, 0.4310	0.0433, 0.4809	
Proportion Difference - Stratified CMH Method (95% CI)	0.39 (0.13, 0.64)		0.03 (-0.31, 0.37)		
p-value	0.003		0.86		
Proportion Difference - Unstratified CMH Method (95% CI)	0.37 (0.12, 0.61)		0.06 (-0.20, 0.32)		
p-value	0.003		0.63		
Proportion Difference - Unstratified Exact Method (95% CI)	0.37 (0.10, 0.60)		0.06 (-0.23, 0.35)		
p-value	0.009		0.74		
Unadjusted Inverse Relative Risk (95% CI)	0.31 (0.12, 0.81)		0.76 (0.24, 2.38)		
p-value [1]	0.017		0.64		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.30
Unadjusted Inverse Odds Ratio (95% CI)	0.17 (0.05, 0.64)		0.70 (0.16, 3.00)		
p-value [1]	0.009		0.63		
Unadjusted Absolute Risk Difference (95% CI)	0.37 (0.13, 0.61)		0.06 (-0.18, 0.31)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.29 (0.12, 0.70)		0.87 (0.27, 2.80)		
p-value [2]	0.006		0.82		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.26
Non-Responder, n(%)	13 (46.4%)	20 (83.3%)	28 (73.7%)	12 (80.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.3109: Analysis of Rate of RBC Transfusion Independence by Week 24 by Baseline TSS

Randomized Treatment Phase

ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
RBC Transfusion Independent Rate by Week 24					
Responder, n(%)	19 (45.2%)	4 (20.0%)	6 (25.0%)	3 (15.8%)	
95% Exact CI	0.2985, 0.6133	0.0573, 0.4366	0.0977, 0.4671	0.0338, 0.3958	
Proportion Difference - Stratified CMH Method (95% CI)	0.27 (0.03, 0.52)		0.11 (-0.15, 0.37)		
p-value	0.027		0.43		
Proportion Difference - Unstratified CMH Method (95% CI)	0.25 (0.01, 0.49)		0.09 (-0.16, 0.34)		
p-value	0.039		0.47		
Proportion Difference - Unstratified Exact Method (95% CI)	0.25 (-0.01, 0.49)		0.09 (-0.20, 0.38)		
p-value	0.090		0.71		
Unadjusted Inverse Relative Risk (95% CI)	0.44 (0.17, 1.13)		0.63 (0.18, 2.20)		
p-value [1]	0.088		0.47		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.66
Unadjusted Inverse Odds Ratio (95% CI)	0.30 (0.09, 1.06)		0.56 (0.12, 2.63)		
p-value [1]	0.062		0.46		
Unadjusted Absolute Risk Difference (95% CI)	0.25 (0.02, 0.48)		0.09 (-0.15, 0.33)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.42 (0.17, 1.04)		0.59 (0.17, 2.01)		
p-value [2]	0.061		0.40		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.65
Non-Responder, n(%)	23 (54.8%)	16 (80.0%)	18 (75.0%)	16 (84.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.3101: Analysis of Rate of RBC Transfusion Independence by Week 24
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
RBC Transfusion Independent Rate by Week 24			
Responder, n(%)	25 (37.9%)	7 (17.9%)	32 (30.5%)
95% Exact CI	0.2622, 0.5066	0.0754, 0.3353	0.2187, 0.4022
Proportion Difference - Stratified CMH Method (95% CI)	0.20 (0.02, 0.38)		
p-value	0.028		
Proportion Difference - Unstratified CMH Method (95% CI)	0.20 (0.03, 0.37)		
p-value	0.023		
Proportion Difference - Unstratified Exact Method (95% CI)	0.20 (0.00, 0.39)		
p-value	0.047		
Unadjusted Inverse Relative Risk (95% CI)	0.47 (0.23, 0.99)		
p-value [1]	0.048		
Unadjusted Inverse Odds Ratio (95% CI)	0.36 (0.14, 0.93)		
p-value [1]	0.036		
Unadjusted Absolute Risk Difference (95% CI)	0.20 (0.03, 0.37)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.47 (0.23, 0.97)		
p-value [2]	0.041		
Non-Responder, n(%)	41 (62.1%)	32 (82.1%)	73 (69.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.3502: Analysis of Rate of RBC Transfusion Independent by Week 24
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
RBC Transfusion Independent Rate by Week 24			
Responder, n(%)	22 (36.1%)	3 (10.0%)	25 (27.5%)
95% Exact CI	0.2416, 0.4937	0.0211, 0.2653	0.1863, 0.3783
Proportion Difference - Stratified CMH Method (95% CI)	0.24 (0.05, 0.42)		
p-value	0.012		
Proportion Difference - Unstratified CMH Method (95% CI)	0.26 (0.09, 0.43)		
p-value	0.002		
Proportion Difference - Unstratified Exact Method (95% CI)	0.26 (0.05, 0.46)		
p-value	0.012		
Unadjusted Inverse Relative Risk (95% CI)	0.28 (0.09, 0.85)		
p-value [1]	0.025		
Unadjusted Inverse Odds Ratio (95% CI)	0.20 (0.05, 0.72)		
p-value [1]	0.014		
Unadjusted Absolute Risk Difference (95% CI)	0.26 (0.10, 0.42)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Non-Responder, n(%)	39 (63.9%)	27 (90.0%)	66 (72.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

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Table 2.3503: Analysis of Rate of RBC Transfusion Independent by Week 24
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	MMB (N=52)	BAT (N=25)	Total (N=77)
RBC Transfusion Independent Rate by Week 24			
Responder, n(%)	19 (36.5%)	3 (12.0%)	22 (28.6%)
95% Exact CI	0.2362, 0.5104	0.0255, 0.3122	0.1885, 0.4000
Proportion Difference - Stratified CMH Method (95% CI)	0.23 (0.03, 0.43)		
p-value	0.022		
Proportion Difference - Unstratified CMH Method (95% CI)	0.25 (0.06, 0.44)		
p-value	0.011		
Proportion Difference - Unstratified Exact Method (95% CI)	0.25 (0.01, 0.46)		
p-value	0.032		
Unadjusted Inverse Relative Risk (95% CI)	0.33 (0.11, 1.01)		
p-value [1]	0.051		
Unadjusted Inverse Odds Ratio (95% CI)	0.24 (0.06, 0.90)		
p-value [1]	0.034		
Unadjusted Absolute Risk Difference (95% CI)	0.25 (0.06, 0.43)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.35 (0.11, 1.07)		
p-value [2]	0.065		
Non-Responder, n(%)	33 (63.5%)	22 (88.0%)	55 (71.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline TSS (<18, >=18) as covariates.

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Table 2.3501: Analysis of Rate of RBC Transfusion Independent by Week 24
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=5)	BAT (N=9)	Total (N=14)
RBC Transfusion Independent Rate by Week 24			
Responder, n(%)	3 (60.0%)	4 (44.4%)	7 (50.0%)
95% Exact CI	0.1466, 0.9473	0.1370, 0.7880	0.2304, 0.7696
Proportion Difference - Stratified CMH Method (95% CI)	0.16 (-0.52, 0.83)		
p-value	0.65		
Proportion Difference - Unstratified CMH Method (95% CI)	0.16 (-0.44, 0.75)		
p-value	0.61		
Proportion Difference - Unstratified Exact Method (95% CI)	0.16 (-0.40, 0.64)		
p-value	1.00		
Unadjusted Inverse Relative Risk (95% CI)	0.74 (0.27, 2.06)		
p-value [1]	0.57		
Unadjusted Inverse Odds Ratio (95% CI)	0.53 (0.06, 4.91)		
p-value [1]	0.58		
Unadjusted Absolute Risk Difference (95% CI)	0.16 (-0.38, 0.69)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.74 (0.27, 2.06)		
p-value [2]	0.57		
Non-Responder, n(%)	2 (40.0%)	5 (55.6%)	7 (50.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline TSS (<18, >=18) as covariates.

Table 2.5202: Analysis of response rate of no Transfusion of Any Type for 24 weeks by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Any Type Transfusion Free Rate					
Responder, n(%)	5 (20.8%)	1 (11.1%)	7 (16.7%)	3 (10.0%)	
95% Exact CI	0.0713, 0.4215	0.0028, 0.4825	0.0697, 0.3136	0.0211, 0.2653	
Proportion Difference - Unstratified Exact Method (95% CI)	0.10 (-0.29, 0.46)		0.07 (-0.17, 0.30)		
p-value	1.00		0.51		
Unadjusted Inverse Relative Risk (95% CI)	0.53 (0.07, 3.96)		0.60 (0.17, 2.13)		
p-value [1]	0.54		0.43		
Unadjusted interaction test for Treatment*Age Group [3]					0.92
Unadjusted Inverse Odds Ratio (95% CI)	0.48 (0.05, 4.74)		0.56 (0.13, 2.35)		
p-value [1]	0.53		0.42		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.16, 0.36)		0.07 (-0.09, 0.22)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.43 (0.15, 1.23)		
p-value [2]	NE		0.12		
Adjusted interaction test for Treatment*Age Group [3]					0.88
Non-responder, n(%)	19 (79.2%)	8 (88.9%)	35 (83.3%)	27 (90.0%)	
Any Type Transfusion within 24 weeks	19 (79.2%)	7 (77.8%)	34 (81.0%)	26 (86.7%)	
Discontinued prior to week 24	0	1 (11.1%)	1 (2.4%)	1 (3.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.5207: Analysis of response rate of no Transfusion of Any Type for 24 weeks by Baseline Hemoglobin Level

Randomized Treatment Phase

ITT-Anemic Analysis Set

	HGB <8g/dL		HGB >=8g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Any Type Transfusion Free Rate					
Responder, n(%)	1 (3.7%)	0	11 (28.2%)	4 (12.1%)	
95% Exact CI	0.0009, 0.1897	0.0000, 0.4593	0.1500, 0.4487	0.0340, 0.2820	
Proportion Difference - Unstratified Exact Method (95% CI)	0.04 (-0.41, 0.48)		0.16 (-0.07, 0.38)		
p-value	1.00		0.15		
Unadjusted Inverse Relative Risk (95% CI)	1.33 (0.06, 29.35)		0.43 (0.15, 1.22)		
p-value [1]	0.86		0.11		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Unadjusted Inverse Odds Ratio (95% CI)	1.36 (0.05, 37.35)		0.35 (0.10, 1.23)		
p-value [1]	0.86		0.10		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.23, 0.19)		0.16 (-0.02, 0.34)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.42 (0.16, 1.14)		
p-value [2]	NE		0.089		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Non-responder, n(%)	26 (96.3%)	6 (100.0%)	28 (71.8%)	29 (87.9%)	
Any Type Transfusion within 24 weeks	26 (96.3%)	6 (100.0%)	27 (69.2%)	27 (81.8%)	
Discontinued prior to week 24	0	0	1 (2.6%)	2 (6.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.5206: Analysis of response rate of no Transfusion of Any Type for 24 weeks by Baseline DIPSS Two-Level Risk

Randomized Treatment Phase

ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Any Type Transfusion Free Rate					
Responder, n(%)	8 (16.3%)	4 (12.9%)	4 (23.5%)	0	
95% Exact CI	0.0732, 0.2966	0.0363, 0.2983	0.0681, 0.4990	0.0000, 0.3694	
Proportion Difference - Unstratified Exact Method (95% CI)	0.03 (-0.19, 0.25)		0.24 (-0.17, 0.60)		
p-value	0.76		0.27		
Unadjusted Inverse Relative Risk (95% CI)	0.79 (0.26, 2.40)		0.22 (0.01, 3.69)		
p-value [1]	0.68		0.29		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NE
Unadjusted Inverse Odds Ratio (95% CI)	0.76 (0.21, 2.77)		0.18 (0.01, 3.71)		
p-value [1]	0.68		0.26		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.12, 0.19)		0.19 (-0.06, 0.44)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.51 (0.20, 1.32)		NE		
p-value [2]	0.17		NE		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NE
Non-responder, n(%)	41 (83.7%)	27 (87.1%)	13 (76.5%)	8 (100.0%)	
Any Type Transfusion within 24 weeks	41 (83.7%)	26 (83.9%)	12 (70.6%)	7 (87.5%)	
Discontinued prior to week 24	0	1 (3.2%)	1 (5.9%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.5205: Analysis of response rate of no Transfusion of Any Type for 24 weeks by Baseline DIPSS Three-Level Risk

Randomized Treatment Phase

ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Any Type Transfusion Free Rate				
Responder, n(%)	2 (40.0%)	0	6 (13.6%)	4 (16.7%)
95% Exact CI	0.0527, 0.8534	0.0000, 0.4096	0.0517, 0.2735	0.0474, 0.3738
Proportion Difference - Unstratified Exact Method (95% CI)	0.40 (-0.17, 0.85)		-0.03 (-0.28, 0.22)	
p-value	0.15		0.73	
Unadjusted Inverse Relative Risk (95% CI)	0.15 (0.01, 2.58)		1.22 (0.38, 3.91)	
p-value [1]	0.19		0.74	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.09 (0.00, 2.51)		1.27 (0.32, 5.02)	
p-value [1]	0.16		0.74	
Unadjusted Absolute Risk Difference (95% CI)	0.35 (-0.07, 0.78)		-0.03 (-0.21, 0.15)	
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.77 (0.29, 2.07)	
p-value [2]	NE		0.61	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-responder, n(%)	3 (60.0%)	7 (100.0%)	38 (86.4%)	20 (83.3%)
Any Type Transfusion within 24 weeks	3 (60.0%)	7 (100.0%)	38 (86.4%)	19 (79.2%)
Discontinued prior to week 24	0	0	0	1 (4.2%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.5205: Analysis of response rate of no Transfusion of Any Type for 24 weeks by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=17)	High Risk BAT (N=8)	p-value
Any Type Transfusion Free Rate			
Responder, n(%)	4 (23.5%)	0	
95% Exact CI	0.0681, 0.4990	0.0000, 0.3694	
Proportion Difference - Unstratified Exact Method (95% CI)	0.24 (-0.17, 0.60)		
p-value	0.27		
Unadjusted Inverse Relative Risk (95% CI)	0.22 (0.01, 3.69)		
p-value [1]	0.29		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NE
Unadjusted Inverse Odds Ratio (95% CI)	0.18 (0.01, 3.71)		
p-value [1]	0.26		
Unadjusted Absolute Risk Difference (95% CI)	0.19 (-0.06, 0.44)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NE
Non-responder, n(%)	13 (76.5%)	8 (100.0%)	
Any Type Transfusion within 24 weeks	12 (70.6%)	7 (87.5%)	
Discontinued prior to week 24	1 (5.9%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.5208: Analysis of response rate of no Transfusion of Any Type for 24 weeks by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Any Type Transfusion Free Rate				
Responder, n(%)	9 (20.0%)	2 (8.7%)	2 (15.4%)	1 (12.5%)
95% Exact CI	0.0958, 0.3460	0.0107, 0.2804	0.0192, 0.4545	0.0032, 0.5265
Proportion Difference - Unstratified Exact Method (95% CI)	0.11 (-0.14, 0.35)		0.03 (-0.40, 0.44)	
p-value	0.31		1.00	
Unadjusted Inverse Relative Risk (95% CI)	0.43 (0.10, 1.85)		0.81 (0.09, 7.58)	
p-value [1]	0.26		0.86	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.38 (0.08, 1.93)		0.79 (0.06, 10.38)	
p-value [1]	0.24		0.85	
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.05, 0.28)		0.03 (-0.27, 0.33)	
Adjusted Inverse Relative Risk (95% CI) [2]	0.42 (0.11, 1.61)		NE	
p-value [2]	0.20		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-responder, n(%)	36 (80.0%)	21 (91.3%)	11 (84.6%)	7 (87.5%)
Any Type Transfusion within 24 weeks	35 (77.8%)	21 (91.3%)	11 (84.6%)	5 (62.5%)
Discontinued prior to week 24	1 (2.2%)	0	0	2 (25.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-sg-at-nt24-rt-gba.sas V.03.05 Output file: t-sg-at-nt24-rt-gba-mf.pdf 24AUG2023:16:46

Table 2.5208: Analysis of response rate of no Transfusion of Any Type for 24 weeks by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=8)	Post-PV Myelofibrosis BAT (N=8)	p-value
Any Type Transfusion Free Rate			
Responder, n(%)	1 (12.5%)	1 (12.5%)	
95% Exact CI	0.0032, 0.5265	0.0032, 0.5265	
Proportion Difference - Unstratified Exact Method (95% CI)	0.00 (-0.51, 0.51)		
p-value	1.00		
Unadjusted Inverse Relative Risk (95% CI)	1.00 (0.07, 13.37)		
p-value [1]	1.00		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.82
Unadjusted Inverse Odds Ratio (95% CI)	1.00 (0.05, 19.36)		
p-value [1]	1.00		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.32, 0.32)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.91
Non-responder, n(%)	7 (87.5%)	7 (87.5%)	
Any Type Transfusion within 24 weeks	7 (87.5%)	7 (87.5%)	
Discontinued prior to week 24	0	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.5204: Analysis of response rate of no Transfusion of Any Type for 24 weeks by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Any Type Transfusion Free Rate					
Responder, n(%)	7 (24.1%)	2 (28.6%)	5 (13.5%)	2 (6.3%)	
95% Exact CI	0.1030, 0.4354	0.0367, 0.7096	0.0454, 0.2877	0.0077, 0.2081	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.04 (-0.46, 0.36)		0.07 (-0.16, 0.30)		
p-value	1.00		0.44		
Unadjusted Inverse Relative Risk (95% CI)	1.18 (0.31, 4.51)		0.46 (0.10, 2.22)		
p-value [1]	0.80		0.34		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	1.26 (0.20, 7.97)		0.43 (0.08, 2.37)		
p-value [1]	0.81		0.33		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.41, 0.32)		0.07 (-0.07, 0.21)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-responder, n(%)	22 (75.9%)	5 (71.4%)	32 (86.5%)	30 (93.8%)	
Any Type Transfusion within 24 weeks	21 (72.4%)	4 (57.1%)	32 (86.5%)	29 (90.6%)	
Discontinued prior to week 24	1 (3.4%)	1 (14.3%)	0	1 (3.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.5203: Analysis of response rate of no Transfusion of Any Type for 24 weeks by Gender

Randomized Treatment Phase

ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Any Type Transfusion Free Rate					
Responder, n(%)	10 (19.2%)	1 (5.6%)	2 (14.3%)	3 (14.3%)	
95% Exact CI	0.0963, 0.3253	0.0014, 0.2729	0.0178, 0.4281	0.0305, 0.3634	
Proportion Difference - Unstratified Exact Method (95% CI)	0.14 (-0.13, 0.40)		0.00 (-0.34, 0.34)		
p-value	0.27		1.00		
Unadjusted Inverse Relative Risk (95% CI)	0.29 (0.04, 2.10)		1.00 (0.19, 5.24)		
p-value [1]	0.22		1.00		
Unadjusted interaction test for Treatment*Gender [3]					0.30
Unadjusted Inverse Odds Ratio (95% CI)	0.25 (0.03, 2.08)		1.00 (0.14, 6.91)		
p-value [1]	0.20		1.00		
Unadjusted Absolute Risk Difference (95% CI)	0.14 (-0.01, 0.29)		0.00 (-0.24, 0.24)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.30 (0.05, 1.88)		0.46 (0.09, 2.32)		
p-value [2]	0.20		0.34		
Adjusted interaction test for Treatment*Gender [3]					0.57
Non-responder, n(%)	42 (80.8%)	17 (94.4%)	12 (85.7%)	18 (85.7%)	
Any Type Transfusion within 24 weeks	41 (78.8%)	16 (88.9%)	12 (85.7%)	17 (81.0%)	
Discontinued prior to week 24	1 (1.9%)	1 (5.6%)	0	1 (4.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.5210: Analysis of response rate of no Transfusion of Any Type for 24 weeks by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Any Type Transfusion Free Rate					
Responder, n(%)	5 (17.9%)	3 (12.5%)	7 (18.4%)	1 (6.7%)	
95% Exact CI	0.0606, 0.3689	0.0266, 0.3236	0.0774, 0.3433	0.0017, 0.3195	
Proportion Difference - Unstratified Exact Method (95% CI)	0.05 (-0.22, 0.32)		0.12 (-0.18, 0.40)		
p-value	0.71		0.42		
Unadjusted Inverse Relative Risk (95% CI)	0.70 (0.19, 2.63)		0.36 (0.05, 2.70)		
p-value [1]	0.60		0.32		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.66 (0.14, 3.09)		0.32 (0.04, 2.82)		
p-value [1]	0.60		0.30		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.14, 0.25)		0.12 (-0.06, 0.29)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-responder, n(%)	23 (82.1%)	21 (87.5%)	31 (81.6%)	14 (93.3%)	
Any Type Transfusion within 24 weeks	23 (82.1%)	20 (83.3%)	30 (78.9%)	13 (86.7%)	
Discontinued prior to week 24	0	1 (4.2%)	1 (2.6%)	1 (6.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.5209: Analysis of response rate of no Transfusion of Any Type for 24 weeks by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Any Type Transfusion Free Rate					
Responder, n(%)	8 (19.0%)	2 (10.0%)	4 (16.7%)	2 (10.5%)	
95% Exact CI	0.0860, 0.3412	0.0123, 0.3170	0.0474, 0.3738	0.0130, 0.3314	
Proportion Difference - Unstratified Exact Method (95% CI)	0.09 (-0.18, 0.35)		0.06 (-0.24, 0.35)		
p-value	0.48		0.68		
Unadjusted Inverse Relative Risk (95% CI)	0.53 (0.12, 2.25)		0.63 (0.13, 3.09)		
p-value [1]	0.39		0.57		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.87
Unadjusted Inverse Odds Ratio (95% CI)	0.47 (0.09, 2.46)		0.59 (0.10, 3.62)		
p-value [1]	0.37		0.57		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.09, 0.27)		0.06 (-0.14, 0.26)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.41 (0.12, 1.44)		0.57 (0.13, 2.45)		
p-value [2]	0.16		0.45		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.83
Non-responder, n(%)	34 (81.0%)	18 (90.0%)	20 (83.3%)	17 (89.5%)	
Any Type Transfusion within 24 weeks	34 (81.0%)	17 (85.0%)	19 (79.2%)	16 (84.2%)	
Discontinued prior to week 24	0	1 (5.0%)	1 (4.2%)	1 (5.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.3811: Analysis of Time to RBC Transfusion Independent Response
Randomized Treatment Phase
ITT-Anemic Analysis Set who are not Transfusion Independent at baseline but at any Post-baseline

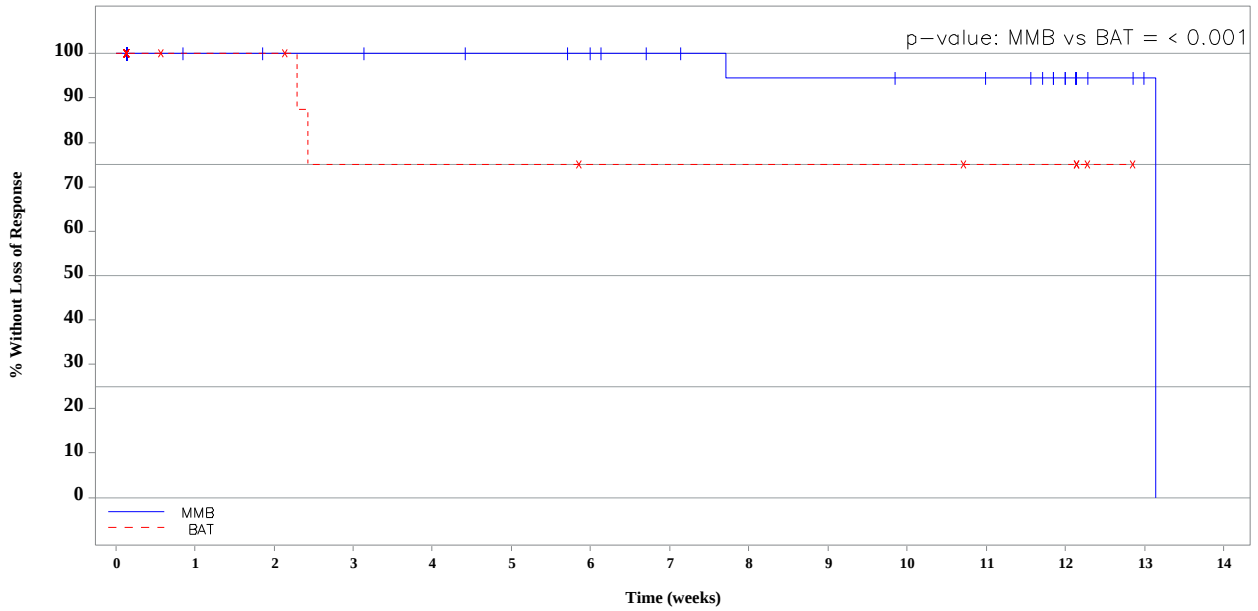
	MMB (N=22)	BAT (N=3)
Subjects with Event		
RBC Transfusion Independent Response, n(%)	**22 (100.0%)**	**3 (100.0%)**
Censor		
Subjects Censored, n(%)	**0**	**0**
Kaplan-Meier Estimate of Time to RBC Transfusion Independent Response (Weeks)		
25-percentile (95% CI)	**12.14 (NE, NE)**	**14.43 (14.43, NE)**
Median (95% CI)	**12.29 (12.14, 17.57)**	**17.00 (14.43, NE)**
75-percentile (95% CI)	**18.14 (12.29, 22.14)**	**23.86 (14.43, NE)**
Min, Max	**12.14, 22.43**	**14.43, 23.86**
Stratified Log-Rank Test p-value	**0.47**	
Adjusted Inverse Hazard Ratio (95% CI)	**0.32 (0.06, 1.59)**	
Unstratified Log-Rank Test p-value	**0.15**	
Unadjusted Inverse Hazard Ratio (95% CI)	**0.35 (0.08, 1.52)**	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

2.6.2 TF

Figure 2.2501: Kaplan-Meier Plot of Duration of Any Type Transfusion Free Response
Randomized Treatment Phase
ITT-Anemic Analysis Set



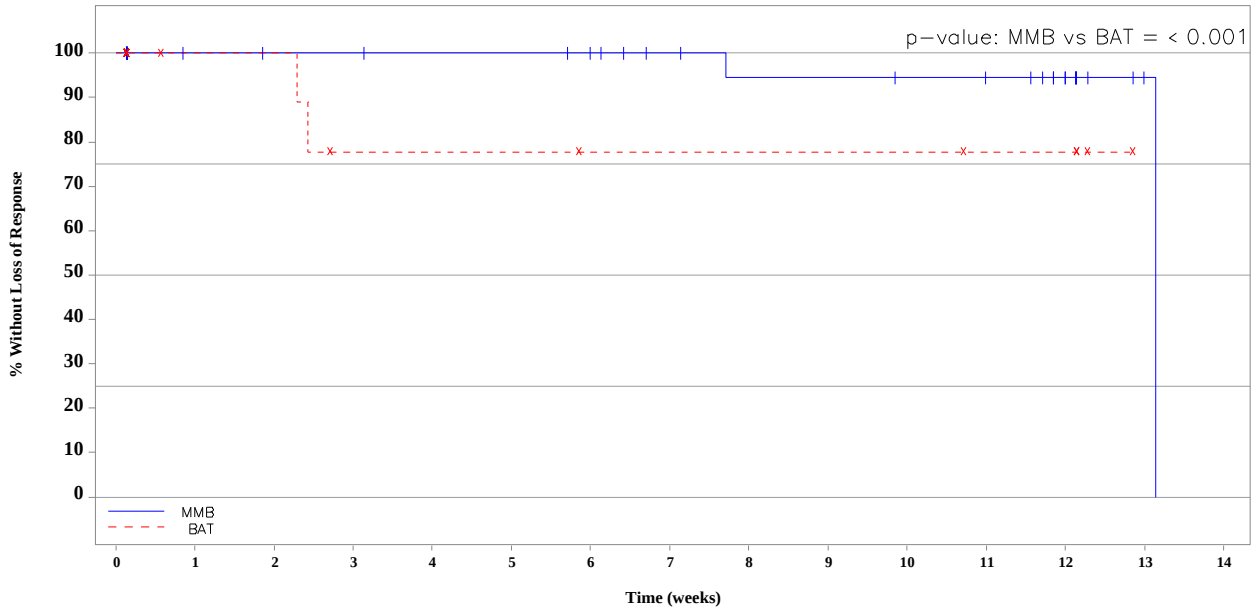
N at Risk (Events)

MMB	66 (0)	26 (0)	25 (0)	25 (0)	24 (0)	23 (0)	22 (0)	19 (0)	17 (1)	17 (1)	16 (1)	16 (1)	11 (1)	2 (1)	0 (2)
BAT	39 (0)	9 (0)	9 (0)	6 (2)	6 (2)	6 (2)	5 (2)	5 (2)	5 (2)	5 (2)	5 (2)	4 (2)	4 (2)	0 (2)	0 (2)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-dur-any-tfr.sas V.03.05 Output file: g-dur-any-tfr.pdf 25AUG2023:12:36

Figure 2.2301: Kaplan-Meier Plot of Duration of RBC Transfusion Free Response
Randomized Treatment Phase
ITT-Anemic Analysis Set



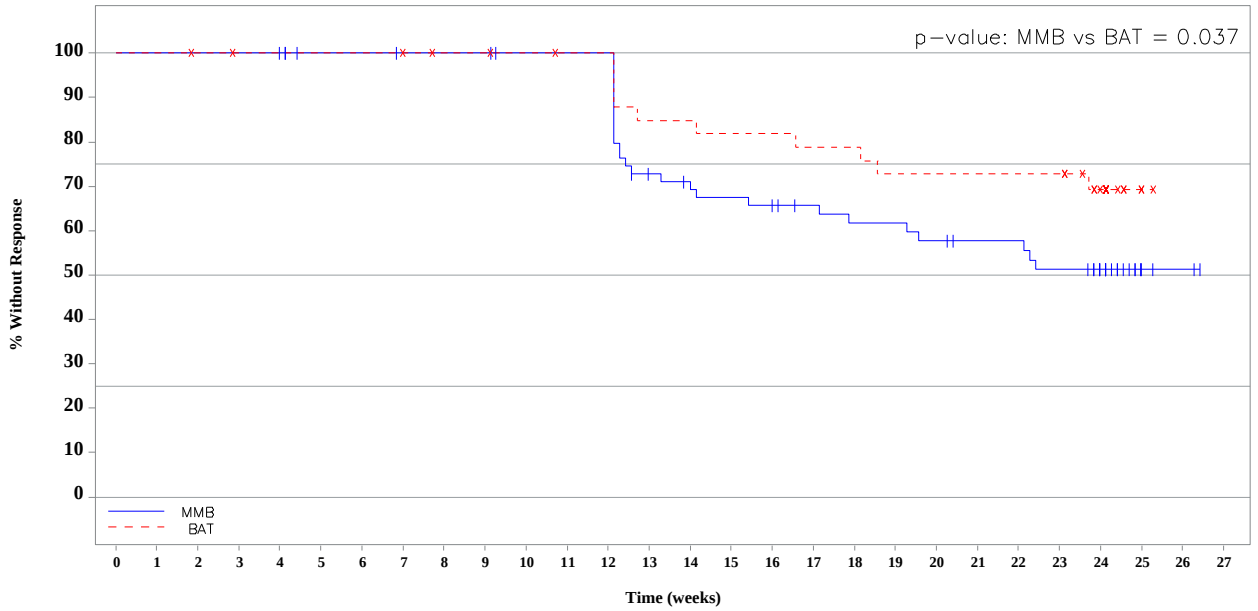
N at Risk (Events)

MMB	66 (0)	26 (0)	25 (0)	25 (0)	24 (0)	24 (0)	23 (0)	19 (0)	17 (1)	17 (1)	16 (1)	16 (1)	11 (1)	2 (1)	0 (2)
BAT	39 (0)	9 (0)	9 (0)	6 (2)	6 (2)	6 (2)	5 (2)	5 (2)	5 (2)	5 (2)	5 (2)	4 (2)	4 (2)	0 (2)	0 (2)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-dur-rbc-tfr.sas V.03.05 Output file: g-dur-rbc-tfr.pdf 25AUG2023:12:35

Figure 2.2601: Kaplan-Meier Plot of Time to Any Type Transfusion Free Response
Randomized Treatment Phase
ITT-Anemic Analysis Set



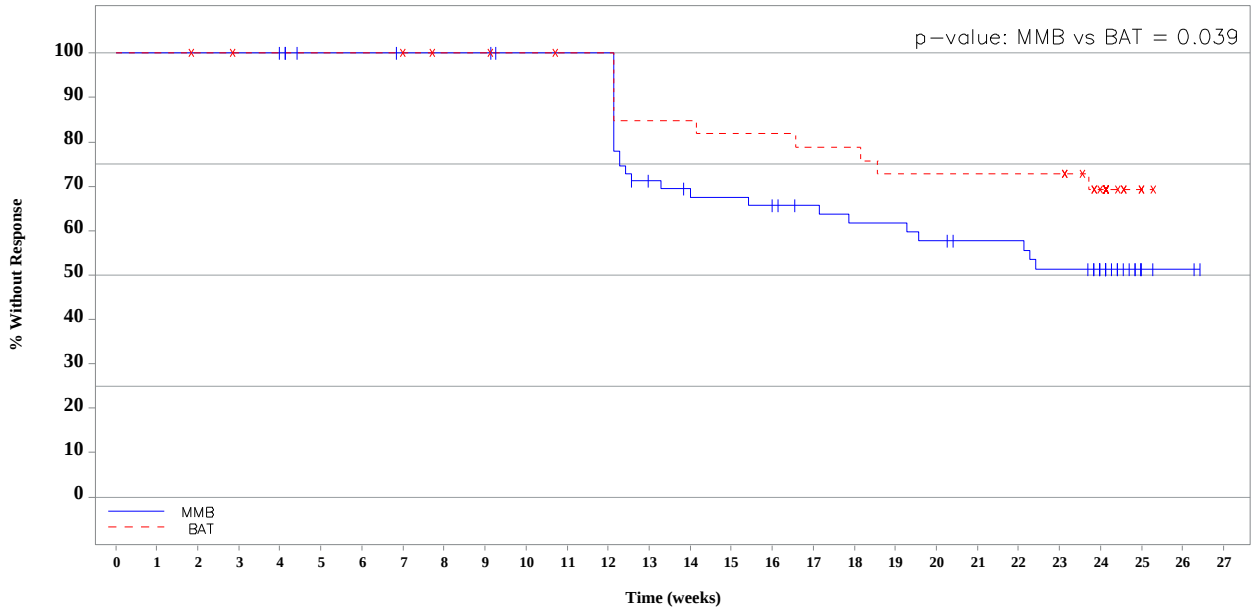
N at Risk (Events)

MMB	66 (0)	66 (0)	66 (0)	66 (0)	66 (0)	62 (0)	62 (0)	61 (0)	61 (0)	61 (0)	59 (0)	59 (0)	59 (0)	42 (16)	39 (18)	37 (19)	36 (20)	33 (20)	31 (22)	31 (22)	29 (24)	27 (24)	27 (24)	24 (27)	21 (27)	6 (27)	2 (27)	0 (27)
BAT	39 (0)	39 (0)	38 (0)	37 (0)	37 (0)	37 (0)	37 (0)	37 (0)	35 (0)	35 (0)	34 (0)	33 (0)	33 (0)	28 (5)	28 (5)	27 (6)	27 (6)	26 (7)	26 (7)	24 (9)	24 (9)	24 (9)	24 (9)	24 (9)	18 (10)	3 (10)	0 (10)	0 (10)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-tte-any-tfr-rt.sas V.03.05 Output file: g-tte-any-tfr-rt.pdf 25AUG2023:12:36

Figure 2.2401: Kaplan-Meier Plot of Time to RBC Transfusion Free Response
Randomized Treatment Phase
ITT-Anemic Analysis Set



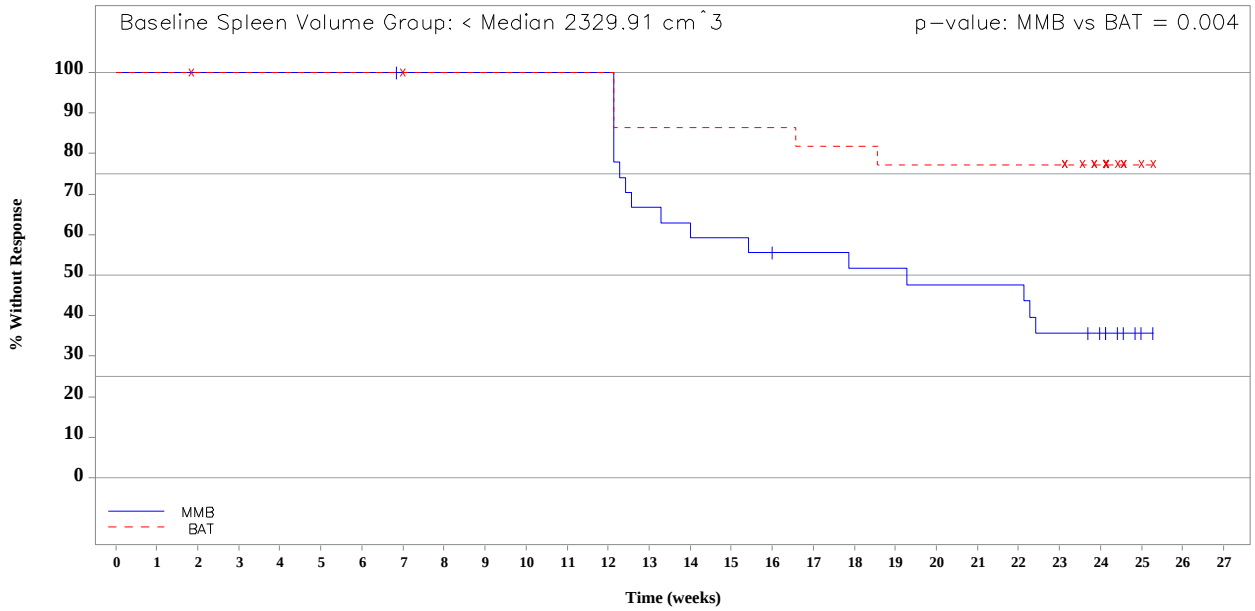
N at Risk (Events)

MMB	66 (0)	66 (0)	66 (0)	66 (0)	66 (0)	62 (0)	62 (0)	61 (0)	61 (0)	61 (0)	59 (0)	59 (0)	59 (0)	41 (17)	38 (19)	37 (19)	36 (20)	33 (20)	31 (22)	31 (22)	29 (24)	27 (24)	27 (24)	24 (27)	21 (27)	6 (27)	2 (27)	0 (27)	
BAT	39 (0)	39 (0)	38 (0)	37 (0)	37 (0)	37 (0)	37 (0)	37 (0)	35 (0)	35 (0)	34 (0)	33 (0)	33 (0)	28 (5)	28 (5)	27 (6)	27 (6)	26 (7)	26 (7)	24 (9)	24 (9)	24 (9)	24 (9)	24 (9)	18 (10)	3 (10)	0 (10)	0 (10)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-tte-tfr-rt.sas V.03.05 Output file: g-tte-tfr-rt.pdf 25AUG2023:12:35

Figure 2.2410: Kaplan-Meier Plot of Time to RBC Transfusion Free Response by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set



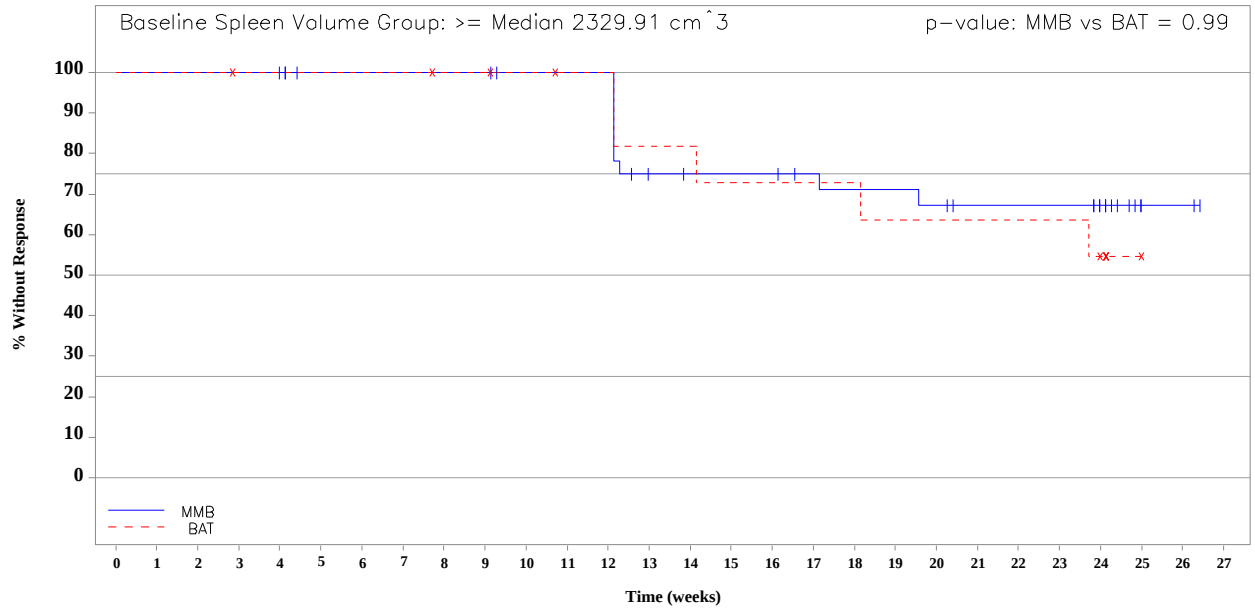
N at Risk (Events)

MMB	28 (0)	28 (0)	28 (0)	28 (0)	28 (0)	28 (0)	28 (0)	27 (0)	27 (0)	27 (0)	27 (0)	27 (0)	27 (0)	18 (9)	17 (11)	16 (11)	15 (12)	14 (12)	13 (13)	13 (13)	12 (14)	12 (14)	12 (14)	9 (17)	8 (17)	2 (17)	0 (17)	0 (17)
BAT	24 (0)	24 (0)	23 (0)	23 (0)	23 (0)	23 (0)	23 (0)	23 (0)	22 (0)	22 (0)	22 (0)	22 (0)	22 (0)	19 (3)	19 (3)	19 (3)	19 (3)	18 (4)	18 (4)	17 (5)	17 (5)	17 (5)	17 (5)	17 (5)	12 (5)	2 (5)	0 (5)	0 (5)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-tte-tfr-sub.sas V.03.05 Output file: g-tte-tfr-svb.pdf 29AUG2023: 8:38

Figure 2.2410: Kaplan-Meier Plot of Time to RBC Transfusion Free Response by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set



N at Risk (Events)

MMB	38 (0)	38 (0)	38 (0)	38 (0)	38 (0)	34 (0)	34 (0)	34 (0)	34 (0)	34 (0)	32 (0)	32 (0)	32 (0)	23 (8)	21 (8)	21 (8)	21 (8)	19 (8)	18 (9)	18 (9)	17 (10)	15 (10)	15 (10)	15 (10)	13 (10)	4 (10)	2 (10)	0 (10)
BAT	15 (0)	15 (0)	15 (0)	14 (0)	14 (0)	14 (0)	14 (0)	14 (0)	13 (0)	13 (0)	12 (0)	11 (0)	11 (0)	9 (2)	9 (2)	8 (3)	8 (3)	8 (3)	8 (3)	7 (4)	7 (4)	7 (4)	7 (4)	7 (4)	6 (5)	1 (5)	0 (5)	0 (5)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-tte-tfr-sub.sas V.03.05 Output file: g-tte-tfr-svb.pdf 29AUG2023: 8:38

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Study GS-US-352-1214

Table 2.5301: Analysis of Rate of Any Type Transfusion Free Response at Week 24 and at Week 12

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Any Type Transfusion Free Rate at Week 24			
Responder, n(%)	11 (16.7%)	4 (10.3%)	15 (14.3%)
95% Exact CI	0.0862, 0.2787	0.0287, 0.2422	0.0822, 0.2247
Proportion Difference - Stratified CMH Method (95% CI)	0.09 (-0.05, 0.23)		
p-value	0.20		
Proportion Difference - Unstratified CMH Method (95% CI)	0.06 (-0.07, 0.20)		
p-value	0.36		
Proportion Difference - Unstratified Exact Method (95% CI)	0.06 (-0.13, 0.26)		
p-value	0.56		
Unadjusted Inverse Relative Risk (95% CI)	0.62 (0.21, 1.80)		
p-value [1]	0.38		
Unadjusted Inverse Odds Ratio (95% CI)	0.57 (0.17, 1.94)		
p-value [1]	0.37		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.07, 0.20)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.52 (0.20, 1.32)		
p-value [2]	0.17		
Non-responder, n(%)	55 (83.3%)	35 (89.7%)	90 (85.7%)
Any Type Transfusion within 12 weeks prior to Week 24	37 (56.1%)	28 (71.8%)	65 (61.9%)
Discontinued prior to week 24	18 (27.3%)	7 (17.9%)	25 (23.8%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

GSK Oncology

Study GS-US-352-1214

Table 2.5301: Analysis of Rate of Any Type Transfusion Free Response at Week 24 and at Week 12

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Any Type Transfusion Free Rate at Week 12			
Responder, n(%)	12 (18.2%)	4 (10.3%)	16 (15.2%)
95% Exact CI	0.0976, 0.2961	0.0287, 0.2422	0.0897, 0.2356
Proportion Difference - Stratified CMH Method (95% CI)	0.11 (-0.03, 0.25)		
p-value	0.14		
Proportion Difference - Unstratified CMH Method (95% CI)	0.08 (-0.06, 0.22)		
p-value	0.26		
Proportion Difference - Unstratified Exact Method (95% CI)	0.08 (-0.12, 0.27)		
p-value	0.40		
Unadjusted Inverse Relative Risk (95% CI)	0.56 (0.20, 1.63)		
p-value [1]	0.29		
Unadjusted Inverse Odds Ratio (95% CI)	0.51 (0.15, 1.72)		
p-value [1]	0.28		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.05, 0.21)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.47 (0.19, 1.21)		
p-value [2]	0.12		
Non-responder, n(%)	54 (81.8%)	35 (89.7%)	89 (84.8%)
Any Type Transfusion within 12 weeks prior to Week 12	47 (71.2%)	29 (74.4%)	76 (72.4%)
Discontinued prior to week 12	7 (10.6%)	6 (15.4%)	13 (12.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.5101: Analysis of Rate of Any Type Transfusion Free Response by Week 24

Randomized Treatment Phase

ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Any Type Transfusion Free Rate by Week 24 in RT Phase			
Responder, n(%)	20 (30.3%)	9 (23.1%)	29 (27.6%)
Unadjusted Inverse Relative Risk (95% CI)	0.76 (0.39, 1.50)		
p-value [1]	0.43		
Unadjusted Inverse Odds Ratio (95% CI)	0.69 (0.28, 1.72)		
p-value [1]	0.42		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.10, 0.24)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.62 (0.36, 1.06)		
p-value [2]	0.082		
Subjects not Transfusion Free at Baseline, n	53	30	83
New Any Type Transfusion Free Rate by Week 24			
Responder, n/N(%)	7/53 (13.2%)	0	7/83 (8.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

For MMB and BAT group, the baseline is based on any type of transfusion within 84 days prior to or on the date of randomization.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

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Table 2.5402: Analysis of Duration of Any Type Transfusion Free Response by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Subjects with Event					
Loss of Any Type Transfusion Free Response, n(%)	0	0	2 (4.8%)	2 (6.7%)	
Censor					
Subjects Censored, n(%)	24 (100.0%)	9 (100.0%)	40 (95.2%)	28 (93.3%)	
Non-Responder: Censored at Randomization Date	15 (62.5%)	8 (88.9%)	24 (60.0%)	21 (75.0%)	
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	9 (37.5%)	1 (11.1%)	16 (40.0%)	7 (25.0%)	
Kaplan-Meier Estimate of Duration of Any Type Transfusion Free Response (Weeks)					
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	13.14 (7.71, NE)	2.43 (2.29, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	13.14 (NE, NE)	NE (2.29, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	13.14 (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 12.86	0.14, 12.86	0.14, 13.14	0.14, 12.29	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusion of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-any-tfr-sub.sas V.03.05 Output file: t-dur-any-tfr-age.pdf 24AUG2023:16:38

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Table 2.5406: Analysis of Duration of Any Type Transfusion Free Response by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Subjects with Event					
Loss of Any Type Transfusion Free Response, n(%)	1 (2.0%)	1 (3.2%)	1 (5.9%)	1 (12.5%)	
Censor					
Subjects Censored, n(%)	48 (98.0%)	30 (96.8%)	16 (94.1%)	7 (87.5%)	
Non-Responder: Censored at Randomization Date	28 (58.3%)	22 (73.3%)	11 (68.8%)	7 (100.0%)	
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	20 (41.7%)	8 (26.7%)	5 (31.3%)	0	
Kaplan-Meier Estimate of Duration of Any Type Transfusion Free Response (Weeks)					
25-percentile (95% CI)	13.14 (NE, NE)	NE (2.43, NE)	NE (7.71, NE)	2.29 (NE, NE)	
Median (95% CI)	13.14 (NE, NE)	NE (2.43, NE)	NE (7.71, NE)	2.29 (NE, NE)	
75-percentile (95% CI)	13.14 (NE, NE)	NE (NE, NE)	NE (7.71, NE)	2.29 (NE, NE)	
Min, Max	0.14, 13.14	0.14, 12.86	0.14, 12.86	0.14, 2.29	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusion of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-any-tfr-sub.sas V.03.05 Output file: t-dur-any-tfr-dipss2.pdf 24AUG2023:16:38

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Table 2.5405: Analysis of Duration of Any Type Transfusion Free Response by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Subjects with Event				
Loss of Any Type Transfusion Free Response, n(%)	0	0	1 (2.3%)	1 (4.2%)
Censor				
Subjects Censored, n(%)	5 (100.0%)	7 (100.0%)	43 (97.7%)	23 (95.8%)
Non-Responder: Censored at Randomization Date	3 (60.0%)	6 (85.7%)	25 (58.1%)	16 (69.6%)
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	2 (40.0%)	1 (14.3%)	18 (41.9%)	7 (30.4%)
Kaplan-Meier Estimate of Duration of Any Type Transfusion Free Response (Weeks)				
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	13.14 (NE, NE)	NE (2.43, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	13.14 (NE, NE)	NE (2.43, NE)
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	13.14 (NE, NE)	NE (NE, NE)
Min, Max	0.14, 11.86	0.14, 10.71	0.14, 13.14	0.14, 12.86
Stratified Log-Rank Test p-value	NA		NA	
Adjusted Hazard Ratio (95% CI)	NA		NA	
Unstratified Log-Rank Test p-value	NA		NA	
Unadjusted Hazard Ratio (95% CI)	NA		NA	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusion of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-any-tfr-sub.sas V.03.05 Output file: t-dur-any-tfr-dipss3.pdf 24AUG2023:16:38

Table 2.5405: Analysis of Duration of Any Type Transfusion Free Response by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=17)	High Risk BAT (N=8)	p-value
Subjects with Event			
Loss of Any Type Transfusion Free Response, n(%)	1 (5.9%)	1 (12.5%)	
Censor			
Subjects Censored, n(%)	16 (94.1%)	7 (87.5%)	
Non-Responder: Censored at Randomization Date	11 (68.8%)	7 (100.0%)	
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	5 (31.3%)	0	
Kaplan-Meier Estimate of Duration of Any Type Transfusion Free Response (Weeks)			
25-percentile (95% CI)	NE (7.71, NE)	2.29 (NE, NE)	
Median (95% CI)	NE (7.71, NE)	2.29 (NE, NE)	
75-percentile (95% CI)	NE (7.71, NE)	2.29 (NE, NE)	
Min, Max	0.14, 12.86	0.14, 2.29	
Stratified Log-Rank Test p-value	NA		
Adjusted Hazard Ratio (95% CI)	NA		
Unstratified Log-Rank Test p-value	NA		
Unadjusted Hazard Ratio (95% CI)	NA		
P-value for interaction test			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusion of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-any-tfr-sub.sas V.03.05 Output file: t-dur-any-tfr-dipss3.pdf 24AUG2023:16:38

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Table 2.5404: Analysis of Duration of Any Type Transfusion Free Response by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Subjects with Event					
Loss of Any Type Transfusion Free Response, n(%)	1 (3.4%)	0	1 (2.7%)	2 (6.3%)	
Censor					
Subjects Censored, n(%)	28 (96.6%)	7 (100.0%)	36 (97.3%)	30 (93.8%)	
Non-Responder: Censored at Randomization Date	16 (57.1%)	5 (71.4%)	23 (63.9%)	24 (80.0%)	
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	12 (42.9%)	2 (28.6%)	13 (36.1%)	6 (20.0%)	
Kaplan-Meier Estimate of Duration of Any Type Transfusion Free Response (Weeks)					
25-percentile (95% CI)	NE (7.71, NE)	NE (NE, NE)	13.14 (NE, NE)	2.43 (2.29, NE)	
Median (95% CI)	NE (7.71, NE)	NE (NE, NE)	13.14 (NE, NE)	NE (2.29, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	13.14 (NE, NE)	NE (2.43, NE)	
Min, Max	0.14, 13.00	0.14, 12.14	0.14, 13.14	0.14, 12.86	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusion of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-any-tfr-sub.sas V.03.05 Output file: t-dur-any-tfr-geo.pdf 24AUG2023:16:38

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Table 2.5407: Analysis of Duration of Any Type Transfusion Free Response by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Subjects with Event					
Loss of Any Type Transfusion Free Response, n(%)	1 (3.7%)	1 (16.7%)	1 (2.6%)	1 (3.0%)	
Censor					
Subjects Censored, n(%)	26 (96.3%)	5 (83.3%)	38 (97.4%)	32 (97.0%)	
Non-Responder: Censored at Randomization Date	17 (65.4%)	5 (100.0%)	22 (57.9%)	24 (75.0%)	
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	9 (34.6%)	0	16 (42.1%)	8 (25.0%)	
Kaplan-Meier Estimate of Duration of Any Type Transfusion Free Response (Weeks)					
25-percentile (95% CI)	NE (7.71, NE)	2.29 (NE, NE)	13.14 (NE, NE)	NE (2.43, NE)	
Median (95% CI)	NE (7.71, NE)	2.29 (NE, NE)	13.14 (NE, NE)	NE (2.43, NE)	
75-percentile (95% CI)	NE (NE, NE)	2.29 (NE, NE)	13.14 (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 13.00	0.14, 2.29	0.14, 13.14	0.14, 12.86	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusion of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-any-tfr-sub.sas V.03.05 Output file: t-dur-any-tfr-hgb.pdf 24AUG2023:16:39

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Table 2.5408: Analysis of Duration of Any Type Transfusion Free Response by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=13)	BAT (N=8)	MMB (N=8)	BAT (N=8)
Subjects with Event				
Loss of Any Type Transfusion Free Response, n(%)	0	0	0	0
Censor				
Subjects Censored, n(%)	13 (100.0%)	8 (100.0%)	8 (100.0%)	8 (100.0%)
Non-Responder: Censored at Randomization Date	8 (61.5%)	6 (75.0%)	5 (62.5%)	6 (75.0%)
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	5 (38.5%)	2 (25.0%)	3 (37.5%)	2 (25.0%)
Kaplan-Meier Estimate of Duration of Any Type Transfusion Free Response (Weeks)				
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Min, Max	0.14, 13.00	0.14, 12.14	0.14, 12.14	0.14, 12.86
Stratified Log-Rank Test p-value	NA		NA	
Adjusted Hazard Ratio (95% CI)	NA		NA	
Unstratified Log-Rank Test p-value	NA		NA	
Unadjusted Hazard Ratio (95% CI)	NA		NA	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusion of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-any-tfr-sub.sas V.03.05 Output file: t-dur-any-tfr-mf.pdf 24AUG2023:16:39

Table 2.5408: Analysis of Duration of Any Type Transfusion Free Response by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Primary Myelofibrosis MMB (N=45)	Primary Myelofibrosis BAT (N=23)	p-value
Subjects with Event			
Loss of Any Type Transfusion Free Response, n(%)	2 (4.4%)	2 (8.7%)	
Censor			
Subjects Censored, n(%)	43 (95.6%)	21 (91.3%)	
Non-Responder: Censored at Randomization Date	26 (60.5%)	17 (81.0%)	
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	17 (39.5%)	4 (19.0%)	
Kaplan-Meier Estimate of Duration of Any Type Transfusion Free Response (Weeks)			
25-percentile (95% CI)	13.14 (7.71, NE)	2.43 (2.29, NE)	
Median (95% CI)	13.14 (NE, NE)	NE (2.29, NE)	
75-percentile (95% CI)	13.14 (NE, NE)	NE (2.29, NE)	
Min, Max	0.14, 13.14	0.14, 12.29	
Stratified Log-Rank Test p-value	NA		
Adjusted Hazard Ratio (95% CI)	NA		
Unstratified Log-Rank Test p-value	NA		
Unadjusted Hazard Ratio (95% CI)	NA		
P-value for interaction test			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusion of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-any-tfr-sub.sas V.03.05 Output file: t-dur-any-tfr-mf.pdf 24AUG2023:16:39

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Table 2.5403: Analysis of Duration of Any Type Transfusion Free Response by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Subjects with Event					
Loss of Any Type Transfusion Free Response, n(%)	2 (3.8%)	2 (11.1%)	0	0	
Censor					
Subjects Censored, n(%)	50 (96.2%)	16 (88.9%)	14 (100.0%)	21 (100.0%)	
Non-Responder: Censored at Randomization Date	33 (66.0%)	14 (87.5%)	6 (42.9%)	15 (71.4%)	
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	17 (34.0%)	2 (12.5%)	8 (57.1%)	6 (28.6%)	
Kaplan-Meier Estimate of Duration of Any Type Transfusion Free Response (Weeks)					
25-percentile (95% CI)	13.14 (7.71, NE)	2.36 (2.29, NE)	NE (NE, NE)	NE (NE, NE)	
Median (95% CI)	13.14 (NE, NE)	NE (2.29, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	13.14 (NE, NE)	NE (2.29, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 13.14	0.14, 12.29	0.14, 13.00	0.14, 12.86	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusion of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-any-tfr-sub.sas V.03.05 Output file: t-dur-any-tfr-sex.pdf 24AUG2023:16:38

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Table 2.5410: Analysis of Duration of Any Type Transfusion Free Response by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Subjects with Event					
Loss of Any Type Transfusion Free Response, n(%)	1 (3.6%)	2 (8.3%)	1 (2.6%)	0	
Censor					
Subjects Censored, n(%)	27 (96.4%)	22 (91.7%)	37 (97.4%)	15 (100.0%)	
Non-Responder: Censored at Randomization Date	11 (40.7%)	19 (86.4%)	28 (75.7%)	10 (66.7%)	
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	16 (59.3%)	3 (13.6%)	9 (24.3%)	5 (33.3%)	
Kaplan-Meier Estimate of Duration of Any Type Transfusion Free Response (Weeks)					
25-percentile (95% CI)	NE (7.71, NE)	2.43 (2.29, NE)	13.14 (NE, NE)	NE (NE, NE)	
Median (95% CI)	NE (7.71, NE)	NE (2.29, NE)	13.14 (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (2.29, NE)	13.14 (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 13.00	0.14, 12.86	0.14, 13.14	0.14, 12.14	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusion of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-any-tfr-sub.sas V.03.05 Output file: t-dur-any-tfr-svb.pdf 24AUG2023:16:39

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Table 2.5409: Analysis of Duration of Any Type Transfusion Free Response by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Subjects with Event					
Loss of Any Type Transfusion Free Response, n(%)	0	1 (5.0%)	2 (8.3%)	1 (5.3%)	
Censor					
Subjects Censored, n(%)	42 (100.0%)	19 (95.0%)	22 (91.7%)	18 (94.7%)	
Non-Responder: Censored at Randomization Date	23 (54.8%)	14 (73.7%)	16 (72.7%)	15 (83.3%)	
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	19 (45.2%)	5 (26.3%)	6 (27.3%)	3 (16.7%)	
Kaplan-Meier Estimate of Duration of Any Type Transfusion Free Response (Weeks)					
25-percentile (95% CI)	NE (NE, NE)	NE (2.43, NE)	13.14 (7.71, NE)	2.29 (2.29, NE)	
Median (95% CI)	NE (NE, NE)	NE (2.43, NE)	13.14 (7.71, NE)	NE (2.29, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (2.43, NE)	13.14 (7.71, NE)	NE (2.29, NE)	
Min, Max	0.14, 13.00	0.14, 12.86	0.14, 13.14	0.14, 12.14	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusion of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment and baseline TD (yes,no).
Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-any-tfr-sub.sas V.03.05 Output file: t-dur-any-tfr-tss.pdf 24AUG2023:16:39

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Table 2.5401: Analysis of Duration of Any Type Transfusion Free Response
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Subjects with Event		
Loss of Any Type Transfusion Free Response, n(%)	2 (3.0%)	2 (5.1%)
Censor		
Subjects Censored, n(%)	64 (97.0%)	37 (94.9%)
Non-Responder: Censored at Randomization Date	39 (60.9%)	29 (78.4%)
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	25 (39.1%)	8 (21.6%)
Kaplan-Meier Estimate of Duration of Any Type Transfusion Free Response (Weeks)		
25-percentile (95% CI)	13.14 (7.71, NE)	NE (2.29, NE)
Median (95% CI)	13.14 (NE, NE)	NE (2.29, NE)
75-percentile (95% CI)	13.14 (NE, NE)	NE (NE, NE)
Min, Max	0.14, 13.14	0.14, 12.86
Stratified Log-Rank Test p-value	< 0.001	
Adjusted Hazard Ratio (95% CI)	<0.01 (<0.01, NE)	
Unstratified Log-Rank Test p-value	0.068	
Unadjusted Hazard Ratio (95% CI)	0.15 (0.01, 1.61)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusion of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
NE = Not estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-any-tfr.sas V.03.05 Output file: t-dur-any-tfr.pdf 24AUG2023:16:36

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Table 2.4902: Analysis of Duration of RBC Transfusion Free Response by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Subjects with Event					
Loss of RBC Transfusion Free Response, n(%)	0	0	2 (4.8%)	2 (6.7%)	
Censor					
Subjects Censored, n(%)	24 (100.0%)	9 (100.0%)	40 (95.2%)	28 (93.3%)	
Non-Responder: Censored at Randomization Date	15 (62.5%)	8 (88.9%)	24 (60.0%)	21 (75.0%)	
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	9 (37.5%)	1 (11.1%)	16 (40.0%)	7 (25.0%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Free Response (Weeks)					
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	13.14 (7.71, NE)	NE (2.29, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	13.14 (NE, NE)	NE (2.29, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	13.14 (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 12.86	0.14, 12.86	0.14, 13.14	0.14, 12.29	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

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Table 2.4906: Analysis of Duration of RBC Transfusion Free Response by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Subjects with Event					
Loss of RBC Transfusion Free Response, n(%)	1 (2.0%)	1 (3.2%)	1 (5.9%)	1 (12.5%)	
Censor					
Subjects Censored, n(%)	48 (98.0%)	30 (96.8%)	16 (94.1%)	7 (87.5%)	
Non-Responder: Censored at Randomization Date	28 (58.3%)	22 (73.3%)	11 (68.8%)	7 (100.0%)	
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	20 (41.7%)	8 (26.7%)	5 (31.3%)	0	
Kaplan-Meier Estimate of Duration of RBC Transfusion Free Response (Weeks)					
25-percentile (95% CI)	13.14 (NE, NE)	NE (2.43, NE)	NE (7.71, NE)	2.29 (NE, NE)	
Median (95% CI)	13.14 (NE, NE)	NE (2.43, NE)	NE (7.71, NE)	2.29 (NE, NE)	
75-percentile (95% CI)	13.14 (NE, NE)	NE (NE, NE)	NE (7.71, NE)	2.29 (NE, NE)	
Min, Max	0.14, 13.14	0.14, 12.86	0.14, 12.86	0.14, 2.29	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-rbc-tfr-sub.sas V.03.05 Output file: t-dur-rbc-tfr-dipss2.pdf 24AUG2023:16:38

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Table 2.4905: Analysis of Duration of RBC Transfusion Free Response by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Subjects with Event				
Loss of RBC Transfusion Free Response, n(%)	0	0	1 (2.3%)	1 (4.2%)
Censor				
Subjects Censored, n(%)	5 (100.0%)	7 (100.0%)	43 (97.7%)	23 (95.8%)
Non-Responder: Censored at Randomization Date	3 (60.0%)	6 (85.7%)	25 (58.1%)	16 (69.6%)
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	2 (40.0%)	1 (14.3%)	18 (41.9%)	7 (30.4%)
Kaplan-Meier Estimate of Duration of RBC Transfusion Free Response (Weeks)				
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	13.14 (NE, NE)	NE (2.43, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	13.14 (NE, NE)	NE (2.43, NE)
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	13.14 (NE, NE)	NE (NE, NE)
Min, Max	0.14, 11.86	0.14, 10.71	0.14, 13.14	0.14, 12.86
Stratified Log-Rank Test p-value	NA		NA	
Adjusted Hazard Ratio (95% CI)	NA		NA	
Unstratified Log-Rank Test p-value	NA		NA	
Unadjusted Hazard Ratio (95% CI)	NA		NA	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-rbc-tfr-sub.sas V.03.05 Output file: t-dur-rbc-tfr-dipss3.pdf 24AUG2023:16:37

Table 2.4905: Analysis of Duration of RBC Transfusion Free Response by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=17)	High Risk BAT (N=8)	p-value
Subjects with Event			
Loss of RBC Transfusion Free Response, n(%)	1 (5.9%)	1 (12.5%)	
Censor			
Subjects Censored, n(%)	16 (94.1%)	7 (87.5%)	
Non-Responder: Censored at Randomization Date	11 (68.8%)	7 (100.0%)	
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	5 (31.3%)	0	
Kaplan-Meier Estimate of Duration of RBC Transfusion Free Response (Weeks)			
25-percentile (95% CI)	NE (7.71, NE)	2.29 (NE, NE)	
Median (95% CI)	NE (7.71, NE)	2.29 (NE, NE)	
75-percentile (95% CI)	NE (7.71, NE)	2.29 (NE, NE)	
Min, Max	0.14, 12.86	0.14, 2.29	
Stratified Log-Rank Test p-value	NA		
Adjusted Hazard Ratio (95% CI)	NA		
Unstratified Log-Rank Test p-value	NA		
Unadjusted Hazard Ratio (95% CI)	NA		
P-value for interaction test			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-rbc-tfr-sub.sas V.03.05 Output file: t-dur-rbc-tfr-dipss3.pdf 24AUG2023:16:37

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Table 2.4904: Analysis of Duration of RBC Transfusion Free Response by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Subjects with Event					
Loss of RBC Transfusion Free Response, n(%)	1 (3.4%)	0	1 (2.7%)	2 (6.3%)	
Censor					
Subjects Censored, n(%)	28 (96.6%)	7 (100.0%)	36 (97.3%)	30 (93.8%)	
Non-Responder: Censored at Randomization Date	16 (57.1%)	5 (71.4%)	23 (63.9%)	24 (80.0%)	
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	12 (42.9%)	2 (28.6%)	13 (36.1%)	6 (20.0%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Free Response (Weeks)					
25-percentile (95% CI)	NE (7.71, NE)	NE (NE, NE)	13.14 (NE, NE)	2.43 (2.29, NE)	
Median (95% CI)	NE (7.71, NE)	NE (NE, NE)	13.14 (NE, NE)	NE (2.29, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	13.14 (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 13.00	0.14, 12.14	0.14, 13.14	0.14, 12.86	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-rbc-tfr-sub.sas V.03.05 Output file: t-dur-rbc-tfr-geo.pdf 24AUG2023:16:37

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Table 2.4907: Analysis of Duration of RBC Transfusion Free Response by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Subjects with Event					
Loss of RBC Transfusion Free Response, n(%)	1 (3.7%)	1 (16.7%)	1 (2.6%)	1 (3.0%)	
Censor					
Subjects Censored, n(%)	26 (96.3%)	5 (83.3%)	38 (97.4%)	32 (97.0%)	
Non-Responder: Censored at Randomization Date	17 (65.4%)	5 (100.0%)	22 (57.9%)	24 (75.0%)	
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	9 (34.6%)	0	16 (42.1%)	8 (25.0%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Free Response (Weeks)					
25-percentile (95% CI)	NE (7.71, NE)	2.29 (NE, NE)	13.14 (NE, NE)	NE (2.43, NE)	
Median (95% CI)	NE (7.71, NE)	2.29 (NE, NE)	13.14 (NE, NE)	NE (2.43, NE)	
75-percentile (95% CI)	NE (NE, NE)	2.29 (NE, NE)	13.14 (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 13.00	0.14, 2.29	0.14, 13.14	0.14, 12.86	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-rbc-tfr-sub.sas V.03.05 Output file: t-dur-rbc-tfr-hgb.pdf 24AUG2023:16:38

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Table 2.4908: Analysis of Duration of RBC Transfusion Free Response by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=13)	BAT (N=8)	MMB (N=8)	BAT (N=8)
Subjects with Event				
Loss of RBC Transfusion Free Response, n(%)	0	0	0	0
Censor				
Subjects Censored, n(%)	13 (100.0%)	8 (100.0%)	8 (100.0%)	8 (100.0%)
Non-Responder: Censored at Randomization Date	8 (61.5%)	6 (75.0%)	5 (62.5%)	6 (75.0%)
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	5 (38.5%)	2 (25.0%)	3 (37.5%)	2 (25.0%)
Kaplan-Meier Estimate of Duration of RBC Transfusion Free Response (Weeks)				
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Min, Max	0.14, 13.00	0.14, 12.14	0.14, 12.14	0.14, 12.86
Stratified Log-Rank Test p-value	NA		NA	
Adjusted Hazard Ratio (95% CI)	NA		NA	
Unstratified Log-Rank Test p-value	NA		NA	
Unadjusted Hazard Ratio (95% CI)	NA		NA	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-rbc-tfr-sub.sas V.03.05 Output file: t-dur-rbc-tfr-mf.pdf 24AUG2023:16:38

Table 2.4908: Analysis of Duration of RBC Transfusion Free Response by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Primary Myelofibrosis MMB (N=45)	Primary Myelofibrosis BAT (N=23)	p-value
Subjects with Event			
Loss of RBC Transfusion Free Response, n(%)	2 (4.4%)	2 (8.7%)	
Censor			
Subjects Censored, n(%)	43 (95.6%)	21 (91.3%)	
Non-Responder: Censored at Randomization Date	26 (60.5%)	17 (81.0%)	
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	17 (39.5%)	4 (19.0%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Free Response (Weeks)			
25-percentile (95% CI)	13.14 (7.71, NE)	2.43 (2.29, NE)	
Median (95% CI)	13.14 (NE, NE)	NE (2.29, NE)	
75-percentile (95% CI)	13.14 (NE, NE)	NE (2.43, NE)	
Min, Max	0.14, 13.14	0.14, 12.29	
Stratified Log-Rank Test p-value	NA		
Adjusted Hazard Ratio (95% CI)	NA		
Unstratified Log-Rank Test p-value	NA		
Unadjusted Hazard Ratio (95% CI)	NA		
P-value for interaction test			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-rbc-tfr-sub.sas V.03.05 Output file: t-dur-rbc-tfr-mf.pdf 24AUG2023:16:38

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Table 2.4903: Analysis of Duration of RBC Transfusion Free Response by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Subjects with Event					
Loss of RBC Transfusion Free Response, n(%)	2 (3.8%)	2 (11.1%)	0	0	
Censor					
Subjects Censored, n(%)	50 (96.2%)	16 (88.9%)	14 (100.0%)	21 (100.0%)	
Non-Responder: Censored at Randomization Date	33 (66.0%)	14 (87.5%)	6 (42.9%)	15 (71.4%)	
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	17 (34.0%)	2 (12.5%)	8 (57.1%)	6 (28.6%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Free Response (Weeks)					
25-percentile (95% CI)	13.14 (7.71, NE)	2.36 (2.29, NE)	NE (NE, NE)	NE (NE, NE)	
Median (95% CI)	13.14 (NE, NE)	NE (2.29, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	13.14 (NE, NE)	NE (2.29, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 13.14	0.14, 12.29	0.14, 13.00	0.14, 12.86	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-rbc-tfr-sub.sas V.03.05 Output file: t-dur-rbc-tfr-sex.pdf 24AUG2023:16:37

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Table 2.4910: Analysis of Duration of RBC Transfusion Free Response by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Subjects with Event					
Loss of RBC Transfusion Free Response, n(%)	1 (3.6%)	2 (8.3%)	1 (2.6%)	0	
Censor					
Subjects Censored, n(%)	27 (96.4%)	22 (91.7%)	37 (97.4%)	15 (100.0%)	
Non-Responder: Censored at Randomization Date	11 (40.7%)	19 (86.4%)	28 (75.7%)	10 (66.7%)	
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	16 (59.3%)	3 (13.6%)	9 (24.3%)	5 (33.3%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Free Response (Weeks)					
25-percentile (95% CI)	NE (7.71, NE)	2.43 (2.29, NE)	13.14 (NE, NE)	NE (NE, NE)	
Median (95% CI)	NE (7.71, NE)	NE (2.29, NE)	13.14 (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (2.29, NE)	13.14 (NE, NE)	NE (NE, NE)	
Min, Max	0.14, 13.00	0.14, 12.86	0.14, 13.14	0.14, 12.14	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-rbc-tfr-sub.sas V.03.05 Output file: t-dur-rbc-tfr-svb.pdf 24AUG2023:16:38

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Table 2.4909: Analysis of Duration of RBC Transfusion Free Response by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Subjects with Event					
Loss of RBC Transfusion Free Response, n(%)	0	1 (5.0%)	2 (8.3%)	1 (5.3%)	
Censor					
Subjects Censored, n(%)	42 (100.0%)	19 (95.0%)	22 (91.7%)	18 (94.7%)	
Non-Responder: Censored at Randomization Date	23 (54.8%)	14 (73.7%)	16 (72.7%)	15 (83.3%)	
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	19 (45.2%)	5 (26.3%)	6 (27.3%)	3 (16.7%)	
Kaplan-Meier Estimate of Duration of RBC Transfusion Free Response (Weeks)					
25-percentile (95% CI)	NE (NE, NE)	NE (2.43, NE)	13.14 (7.71, NE)	2.29 (2.29, NE)	
Median (95% CI)	NE (NE, NE)	NE (2.43, NE)	13.14 (7.71, NE)	NE (2.29, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	13.14 (7.71, NE)	NE (2.29, NE)	
Min, Max	0.14, 13.00	0.14, 12.86	0.14, 13.14	0.14, 12.14	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment and baseline TD (yes,no).
Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-dur-rbc-tfr-sub.sas V.03.05 Output file: t-dur-rbc-tfr-tss.pdf 24AUG2023:16:38

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Table 2.4901: Analysis of Duration of RBC Transfusion Free Response
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Subjects with Event		
Loss of RBC Transfusion Free Response, n(%)	2 (3.0%)	2 (5.1%)
Censor		
Subjects Censored, n(%)	64 (97.0%)	37 (94.9%)
Non-Responder: Censored at Randomization Date	39 (60.9%)	29 (78.4%)
No Loss of Response: Censored at Last Subject Visit Date at RT Phase	25 (39.1%)	8 (21.6%)
Kaplan-Meier Estimate of Duration of RBC Transfusion Free Response (Weeks)		
25-percentile (95% CI)	13.14 (7.71, NE)	NE (2.29, NE)
Median (95% CI)	13.14 (NE, NE)	NE (2.29, NE)
75-percentile (95% CI)	13.14 (NE, NE)	NE (NE, NE)
Min, Max	0.14, 13.14	0.14, 12.86
Stratified Log-Rank Test p-value	< 0.001	
Adjusted Hazard Ratio (95% CI)	<0.01 (<0.01, NE)	
Unstratified Log-Rank Test p-value	0.085	
Unadjusted Hazard Ratio (95% CI)	0.16 (0.01, 1.75)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.4502: RBC Transfusion-free Rate at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
RBC Transfusion Free Rate at Week 24					
Responder, n(%)	8 (33.3%)	1 (11.1%)	14 (33.3%)	6 (20.0%)	
95% Exact CI	0.1563, 0.5532	0.0028, 0.4825	0.1957, 0.4955	0.0771, 0.3857	
Proportion Difference - Stratified CMH Method (95% CI)	0.19 (-0.18, 0.55)		0.15 (-0.06, 0.37)		
p-value	0.31		0.15		
Proportion Difference - Unstratified CMH Method (95% CI)	0.22 (-0.09, 0.54)		0.13 (-0.07, 0.34)		
p-value	0.17		0.21		
Proportion Difference - Unstratified Exact Method (95% CI)	0.22 (-0.16, 0.60)		0.13 (-0.10, 0.36)		
p-value	0.38		0.29		
Unadjusted Inverse Relative Risk (95% CI)	0.33 (0.05, 2.30)		0.60 (0.26, 1.38)		
p-value [1]	0.27		0.23		
Unadjusted interaction test for Treatment*Age Group [3]					0.53
Unadjusted Inverse Odds Ratio (95% CI)	0.25 (0.03, 2.36)		0.50 (0.17, 1.50)		
p-value [1]	0.23		0.22		
Unadjusted Absolute Risk Difference (95% CI)	0.22 (-0.06, 0.50)		0.13 (-0.07, 0.34)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.39 (0.08, 1.93)		0.55 (0.25, 1.23)		
p-value [2]	0.25		0.14		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.4502: RBC Transfusion-free Rate at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Adjusted interaction test for Treatment*Age Group [3]					0.75
Non-responder, n(%)	16 (66.7%)	8 (88.9%)	28 (66.7%)	24 (80.0%)	
RBC Transfusion within 12 weeks prior to Week 24	8 (33.3%)	5 (55.6%)	18 (42.9%)	20 (66.7%)	
Discontinued prior to week 24	8 (33.3%)	3 (33.3%)	10 (23.8%)	4 (13.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.4507: RBC Transfusion-free Rate at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8g/dL		HGB >=8g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
RBC Transfusion Free Rate at Week 24					
Responder, n(%)	8 (29.6%)	0	14 (35.9%)	7 (21.2%)	
95% Exact CI	0.1375, 0.5018	0.0000, 0.4593	0.2120, 0.5282	0.0898, 0.3891	
Proportion Difference - Stratified CMH Method (95% CI)	0.28 (-0.09, 0.65)		0.13 (-0.08, 0.34)		
p-value	0.13		0.23		
Proportion Difference - Unstratified CMH Method (95% CI)	0.30 (0.01, 0.58)		0.15 (-0.06, 0.36)		
p-value	0.043		0.17		
Proportion Difference - Unstratified Exact Method (95% CI)	0.30 (-0.16, 0.72)		0.15 (-0.08, 0.37)		
p-value	0.30		0.20		
Unadjusted Inverse Relative Risk (95% CI)	0.24 (0.02, 3.61)		0.59 (0.27, 1.29)		
p-value [1]	0.30		0.19		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Unadjusted Inverse Odds Ratio (95% CI)	0.18 (0.01, 3.50)		0.48 (0.17, 1.39)		
p-value [1]	0.26		0.18		
Unadjusted Absolute Risk Difference (95% CI)	0.23 (-0.02, 0.49)		0.15 (-0.06, 0.35)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.63 (0.30, 1.30)		
p-value [2]	NE		0.21		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

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Table 2.4507: RBC Transfusion-free Rate at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8g/dL		HGB >=8g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Non-responder, n(%)	19 (70.4%)	6 (100.0%)	25 (64.1%)	26 (78.8%)	
RBC Transfusion within 12 weeks prior to Week 24	11 (40.7%)	4 (66.7%)	15 (38.5%)	21 (63.6%)	
Discontinued prior to week 24	8 (29.6%)	2 (33.3%)	10 (25.6%)	5 (15.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

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Table 2.4506: RBC Transfusion-free Rate at Week 24 by Baseline DIPSS Two-Level Risk

Randomized Treatment Phase

ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
RBC Transfusion Free Rate at Week 24					
Responder, n(%)	18 (36.7%)	7 (22.6%)	4 (23.5%)	0	
95% Exact CI	0.2342, 0.5171	0.0959, 0.4110	0.0681, 0.4990	0.0000, 0.3694	
Proportion Difference - Stratified CMH Method (95% CI)	0.17 (-0.04, 0.37)		0.22 (-0.13, 0.57)		
p-value	0.11		0.21		
Proportion Difference - Unstratified CMH Method (95% CI)	0.14 (-0.06, 0.35)		0.24 (-0.04, 0.51)		
p-value	0.17		0.090		
Proportion Difference - Unstratified Exact Method (95% CI)	0.14 (-0.08, 0.36)		0.24 (-0.17, 0.60)		
p-value	0.22		0.27		
Unadjusted Inverse Relative Risk (95% CI)	0.61 (0.29, 1.30)		0.22 (0.01, 3.69)		
p-value [1]	0.20		0.29		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NE
Unadjusted Inverse Odds Ratio (95% CI)	0.50 (0.18, 1.40)		0.18 (0.01, 3.71)		
p-value [1]	0.19		0.26		
Unadjusted Absolute Risk Difference (95% CI)	0.14 (-0.06, 0.34)		0.19 (-0.06, 0.44)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.56 (0.28, 1.13)		NE		
p-value [2]	0.11		NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.4506: RBC Transfusion-free Rate at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NE
Non-responder, n(%)	31 (63.3%)	24 (77.4%)	13 (76.5%)	8 (100.0%)	
RBC Transfusion within 12 weeks prior to Week 24	19 (38.8%)	18 (58.1%)	7 (41.2%)	7 (87.5%)	
Discontinued prior to week 24	12 (24.5%)	6 (19.4%)	6 (35.3%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

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Table 2.4505: RBC Transfusion-free Rate at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
RBC Transfusion Free Rate at Week 24				
Responder, n(%)	2 (40.0%)	1 (14.3%)	16 (36.4%)	6 (25.0%)
95% Exact CI	0.0527, 0.8534	0.0036, 0.5787	0.2241, 0.5223	0.0977, 0.4671
Proportion Difference - Stratified CMH Method (95% CI)	-0.33 (-1.15, 0.48)		0.15 (-0.08, 0.39)	
p-value	0.42		0.21	
Proportion Difference - Unstratified CMH Method (95% CI)	0.26 (-0.32, 0.83)		0.11 (-0.12, 0.34)	
p-value	0.38		0.33	
Proportion Difference - Unstratified Exact Method (95% CI)	0.26 (-0.32, 0.74)		0.11 (-0.14, 0.36)	
p-value	0.52		0.42	
Unadjusted Inverse Relative Risk (95% CI)	0.36 (0.04, 2.94)		0.69 (0.31, 1.52)	
p-value [1]	0.34		0.36	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.25 (0.02, 4.00)		0.58 (0.19, 1.77)	
p-value [1]	0.33		0.34	
Unadjusted Absolute Risk Difference (95% CI)	0.26 (-0.24, 0.76)		0.11 (-0.11, 0.34)	
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.60 (0.28, 1.29)	
p-value [2]	NE		0.19	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.4505: RBC Transfusion-free Rate at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=17)	High Risk BAT (N=8)	p-value
RBC Transfusion Free Rate at Week 24			
Responder, n(%)	4 (23.5%)	0	
95% Exact CI	0.0681, 0.4990	0.0000, 0.3694	
Proportion Difference - Stratified CMH Method (95% CI)	0.22 (-0.13, 0.57)		
p-value	0.21		
Proportion Difference - Unstratified CMH Method (95% CI)	0.24 (-0.04, 0.51)		
p-value	0.090		
Proportion Difference - Unstratified Exact Method (95% CI)	0.24 (-0.17, 0.60)		
p-value	0.27		
Unadjusted Inverse Relative Risk (95% CI)	0.22 (0.01, 3.69)		
p-value [1]	0.29		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NE
Unadjusted Inverse Odds Ratio (95% CI)	0.18 (0.01, 3.71)		
p-value [1]	0.26		
Unadjusted Absolute Risk Difference (95% CI)	0.19 (-0.06, 0.44)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NE

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

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Table 2.4505: RBC Transfusion-free Rate at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Non-responder, n(%)	3 (60.0%)	6 (85.7%)	28 (63.6%)	18 (75.0%)
RBC Transfusion within 12 weeks prior to Week 24	2 (40.0%)	5 (71.4%)	17 (38.6%)	13 (54.2%)
Discontinued prior to week 24	1 (20.0%)	1 (14.3%)	11 (25.0%)	5 (20.8%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.4505: RBC Transfusion-free Rate at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
(Continued)	MMB (N=17)	BAT (N=8)	p-value
Non-responder, n(%)	13 (76.5%)	8 (100.0%)	
RBC Transfusion within 12 weeks prior to Week 24	7 (41.2%)	7 (87.5%)	
Discontinued prior to week 24	6 (35.3%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

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Table 2.4508: RBC Transfusion-free Rate at Week 24 by Baseline MF Disease Status

Randomized Treatment Phase

ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
RBC Transfusion Free Rate at Week 24				
Responder, n(%)	15 (33.3%)	3 (13.0%)	5 (38.5%)	2 (25.0%)
95% Exact CI	0.2000, 0.4895	0.0278, 0.3359	0.1386, 0.6842	0.0319, 0.6509
Proportion Difference - Stratified CMH Method (95% CI)	0.19 (-0.03, 0.41)		0.06 (-0.38, 0.50)	
p-value	0.096		0.80	
Proportion Difference - Unstratified CMH Method (95% CI)	0.20 (0.00, 0.41)		0.13 (-0.30, 0.57)	
p-value	0.050		0.54	
Proportion Difference - Unstratified Exact Method (95% CI)	0.20 (-0.05, 0.43)		0.13 (-0.31, 0.53)	
p-value	0.088		0.66	
Unadjusted Inverse Relative Risk (95% CI)	0.39 (0.13, 1.22)		0.65 (0.16, 2.59)	
p-value [1]	0.10		0.54	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.30 (0.08, 1.17)		0.53 (0.08, 3.76)	
p-value [1]	0.083		0.53	
Unadjusted Absolute Risk Difference (95% CI)	0.20 (0.01, 0.40)		0.13 (-0.27, 0.53)	
Adjusted Inverse Relative Risk (95% CI) [2]	0.41 (0.14, 1.24)		0.82 (0.20, 3.40)	
p-value [2]	0.11		0.78	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.4508: RBC Transfusion-free Rate at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=8)	Post-PV Myelofibrosis BAT (N=8)	p-value
RBC Transfusion Free Rate at Week 24			
Responder, n(%)	2 (25.0%)	2 (25.0%)	
95% Exact CI	0.0319, 0.6509	0.0319, 0.6509	
Proportion Difference - Stratified CMH Method (95% CI)	0.24 (-0.31, 0.80)		
p-value	0.39		
Proportion Difference - Unstratified CMH Method (95% CI)	0.00 (-0.47, 0.47)		
p-value	1.00		
Proportion Difference - Unstratified Exact Method (95% CI)	0.00 (-0.51, 0.51)		
p-value	1.00		
Unadjusted Inverse Relative Risk (95% CI)	1.00 (0.18, 5.46)		
p-value [1]	1.00		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.65
Unadjusted Inverse Odds Ratio (95% CI)	1.00 (0.10, 9.61)		
p-value [1]	1.00		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.42, 0.42)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.4508: RBC Transfusion-free Rate at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-responder, n(%)	30 (66.7%)	20 (87.0%)	8 (61.5%)	6 (75.0%)
RBC Transfusion within 12 weeks prior to Week 24	18 (40.0%)	16 (69.6%)	4 (30.8%)	4 (50.0%)
Discontinued prior to week 24	12 (26.7%)	4 (17.4%)	4 (30.8%)	2 (25.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.4508: RBC Transfusion-free Rate at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
(Continued)	MMB (N=8)	BAT (N=8)	p-value
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.77
Non-responder, n(%)	6 (75.0%)	6 (75.0%)	
RBC Transfusion within 12 weeks prior to Week 24	4 (50.0%)	5 (62.5%)	
Discontinued prior to week 24	2 (25.0%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.4504: RBC Transfusion-free Rate at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
RBC Transfusion Free Rate at Week 24					
Responder, n(%)	11 (37.9%)	2 (28.6%)	11 (29.7%)	5 (15.6%)	
95% Exact CI	0.2069, 0.5774	0.0367, 0.7096	0.1587, 0.4698	0.0528, 0.3279	
Proportion Difference - Stratified CMH Method (95% CI)	0.14 (-0.27, 0.56)		0.13 (-0.06, 0.32)		
p-value	0.49		0.19		
Proportion Difference - Unstratified CMH Method (95% CI)	0.09 (-0.32, 0.51)		0.14 (-0.06, 0.34)		
p-value	0.66		0.17		
Proportion Difference - Unstratified Exact Method (95% CI)	0.09 (-0.33, 0.49)		0.14 (-0.09, 0.37)		
p-value	1.00		0.25		
Unadjusted Inverse Relative Risk (95% CI)	0.75 (0.21, 2.66)		0.53 (0.20, 1.35)		
p-value [1]	0.66		0.18		
Unadjusted interaction test for Treatment*Region [3]					0.67
Unadjusted Inverse Odds Ratio (95% CI)	0.65 (0.11, 3.97)		0.44 (0.13, 1.43)		
p-value [1]	0.65		0.17		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.28, 0.47)		0.14 (-0.05, 0.33)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.65 (0.24, 1.77)		NE		
p-value [2]	0.40		NE		
Adjusted interaction test for Treatment*Region [3]					0.52

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-sg-rbc-tfr-at-rt-gba.sas V.03.05 Output file: t-rbc-tfr-at-rt-gba-reg.pdf 24AUG2023:16:44

Table 2.4504: RBC Transfusion-free Rate at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Non-responder, n(%)	18 (62.1%)	5 (71.4%)	26 (70.3%)	27 (84.4%)	
RBC Transfusion within 12 weeks prior to Week 24	12 (41.4%)	4 (57.1%)	14 (37.8%)	21 (65.6%)	
Discontinued prior to week 24	6 (20.7%)	1 (14.3%)	12 (32.4%)	6 (18.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.4503: RBC Transfusion-free Rate at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
RBC Transfusion Free Rate at Week 24					
Responder, n(%)	15 (28.8%)	2 (11.1%)	7 (50.0%)	5 (23.8%)	
95% Exact CI	0.1713, 0.4308	0.0138, 0.3471	0.2304, 0.7696	0.0822, 0.4717	
Proportion Difference - Stratified CMH Method (95% CI)	0.16 (-0.07, 0.40)		0.31 (0.02, 0.61)		
p-value	0.17		0.038		
Proportion Difference - Unstratified CMH Method (95% CI)	0.18 (-0.03, 0.38)		0.26 (-0.07, 0.59)		
p-value	0.088		0.12		
Proportion Difference - Unstratified Exact Method (95% CI)	0.18 (-0.09, 0.44)		0.26 (-0.09, 0.57)		
p-value	0.20		0.15		
Unadjusted Inverse Relative Risk (95% CI)	0.39 (0.10, 1.52)		0.48 (0.19, 1.20)		
p-value [1]	0.17		0.12		
Unadjusted interaction test for Treatment*Gender [3]					0.80
Unadjusted Inverse Odds Ratio (95% CI)	0.31 (0.06, 1.51)		0.31 (0.07, 1.33)		
p-value [1]	0.15		0.12		
Unadjusted Absolute Risk Difference (95% CI)	0.18 (-0.01, 0.37)		0.26 (-0.06, 0.58)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.41 (0.11, 1.48)		0.35 (0.11, 1.09)		
p-value [2]	0.17		0.070		
Adjusted interaction test for Treatment*Gender [3]					0.95

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.4503: RBC Transfusion-free Rate at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Non-responder, n(%)	37 (71.2%)	16 (88.9%)	7 (50.0%)	16 (76.2%)	
RBC Transfusion within 12 weeks prior to Week 24	23 (44.2%)	12 (66.7%)	3 (21.4%)	13 (61.9%)	
Discontinued prior to week 24	14 (26.9%)	4 (22.2%)	4 (28.6%)	3 (14.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.4510: RBC Transfusion-free Rate at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
RBC Transfusion Free Rate at Week 24					
Responder, n(%)	13 (46.4%)	3 (12.5%)	9 (23.7%)	4 (26.7%)	
95% Exact CI	0.2751, 0.6613	0.0266, 0.3236	0.1144, 0.4024	0.0779, 0.5510	
Proportion Difference - Stratified CMH Method (95% CI)	0.37 (0.13, 0.61)		-0.08 (-0.44, 0.27)		
p-value	0.002		0.65		
Proportion Difference - Unstratified CMH Method (95% CI)	0.34 (0.10, 0.57)		-0.03 (-0.30, 0.24)		
p-value	0.005		0.83		
Proportion Difference - Unstratified Exact Method (95% CI)	0.34 (0.06, 0.58)		-0.03 (-0.32, 0.27)		
p-value	0.015		1.00		
Unadjusted Inverse Relative Risk (95% CI)	0.27 (0.09, 0.83)		1.13 (0.41, 3.11)		
p-value [1]	0.023		0.82		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.10
Unadjusted Inverse Odds Ratio (95% CI)	0.16 (0.04, 0.68)		1.17 (0.30, 4.60)		
p-value [1]	0.013		0.82		
Unadjusted Absolute Risk Difference (95% CI)	0.34 (0.11, 0.57)		-0.03 (-0.29, 0.23)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.24 (0.09, 0.65)		1.37 (0.51, 3.72)		
p-value [2]	0.005		0.53		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.4510: RBC Transfusion-free Rate at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.065
Non-responder, n(%)	15 (53.6%)	21 (87.5%)	29 (76.3%)	11 (73.3%)	
RBC Transfusion within 12 weeks prior to Week 24	10 (35.7%)	19 (79.2%)	16 (42.1%)	6 (40.0%)	
Discontinued prior to week 24	5 (17.9%)	2 (8.3%)	13 (34.2%)	5 (33.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.4509: RBC Transfusion-free Rate at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
RBC Transfusion Free Rate at Week 24					
Responder, n(%)	18 (42.9%)	4 (20.0%)	4 (16.7%)	3 (15.8%)	
95% Exact CI	0.2772, 0.5904	0.0573, 0.4366	0.0474, 0.3738	0.0338, 0.3958	
Proportion Difference - Stratified CMH Method (95% CI)	0.27 (0.04, 0.49)		0.02 (-0.23, 0.26)		
p-value	0.022		0.89		
Proportion Difference - Unstratified CMH Method (95% CI)	0.23 (-0.01, 0.47)		0.01 (-0.23, 0.24)		
p-value	0.061		0.94		
Proportion Difference - Unstratified Exact Method (95% CI)	0.23 (-0.03, 0.47)		0.01 (-0.28, 0.30)		
p-value	0.095		1.00		
Unadjusted Inverse Relative Risk (95% CI)	0.47 (0.18, 1.20)		0.95 (0.24, 3.73)		
p-value [1]	0.11		0.94		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.43
Unadjusted Inverse Odds Ratio (95% CI)	0.33 (0.10, 1.17)		0.94 (0.18, 4.81)		
p-value [1]	0.086		0.94		
Unadjusted Absolute Risk Difference (95% CI)	0.23 (0.00, 0.46)		0.01 (-0.21, 0.23)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.42 (0.18, 0.99)		0.90 (0.24, 3.43)		
p-value [2]	0.048		0.88		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.4509: RBC Transfusion-free Rate at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.41
Non-responder, n(%)	24 (57.1%)	16 (80.0%)	20 (83.3%)	16 (84.2%)	
RBC Transfusion within 12 weeks prior to Week 24	15 (35.7%)	13 (65.0%)	11 (45.8%)	12 (63.2%)	
Discontinued prior to week 24	9 (21.4%)	3 (15.0%)	9 (37.5%)	4 (21.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.4501: RBC Transfusion-free Rate at Week 24 and Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
RBC Transfusion Free Rate at Week 24			
Responder, n(%)	22 (33.3%)	7 (17.9%)	29 (27.6%)
95% Exact CI	0.2220, 0.4601	0.0754, 0.3353	0.1934, 0.3720
Proportion Difference - Stratified CMH Method (95% CI)	0.16 (-0.01, 0.32)		
p-value	0.066		
Proportion Difference - Unstratified CMH Method (95% CI)	0.15 (-0.02, 0.32)		
p-value	0.074		
Proportion Difference - Unstratified Exact Method (95% CI)	0.15 (-0.05, 0.34)		
p-value	0.11		
Unadjusted Inverse Relative Risk (95% CI)	0.54 (0.25, 1.14)		
p-value [1]	0.11		
Unadjusted Inverse Odds Ratio (95% CI)	0.44 (0.17, 1.15)		
p-value [1]	0.093		
Unadjusted Absolute Risk Difference (95% CI)	0.15 (-0.01, 0.32)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.53 (0.27, 1.07)		
p-value [2]	0.078		
Non-responder, n(%)	44 (66.7%)	32 (82.1%)	76 (72.4%)
RBC Transfusion within 12 weeks prior to Week 24	26 (39.4%)	25 (64.1%)	51 (48.6%)
Discontinued prior to week 24	18 (27.3%)	7 (17.9%)	25 (23.8%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

Table 2.4501: RBC Transfusion-free Rate at Week 24 and Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
RBC Transfusion Free Rate at Week 12			
Responder, n(%)	17 (25.8%)	5 (12.8%)	22 (21.0%)
95% Exact CI	0.1578, 0.3801	0.0430, 0.2743	0.1362, 0.2999
Proportion Difference - Stratified CMH Method (95% CI)	0.15 (0.00, 0.30)		
p-value	0.044		
Proportion Difference - Unstratified CMH Method (95% CI)	0.13 (-0.02, 0.28)		
p-value	0.097		
Proportion Difference - Unstratified Exact Method (95% CI)	0.13 (-0.07, 0.32)		
p-value	0.14		
Unadjusted Inverse Relative Risk (95% CI)	0.50 (0.20, 1.24)		
p-value [1]	0.14		
Unadjusted Inverse Odds Ratio (95% CI)	0.42 (0.14, 1.26)		
p-value [1]	0.12		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.02, 0.28)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.44 (0.20, 0.98)		
p-value [2]	0.045		
Non-responder, n(%)	49 (74.2%)	34 (87.2%)	83 (79.0%)
RBC Transfusion within 12 weeks prior to Week 12	42 (63.6%)	28 (71.8%)	70 (66.7%)
Discontinued prior to week 12	7 (10.6%)	6 (15.4%)	13 (12.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Table 2.4601: Analysis of RBC Transfusion Free Response
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)
RBC Transfusion Free Rate at Baseline in ET Phase			
Responder, n(%)	**9 (20.9%)**	**7 (23.3%)**	**16 (21.9%)**
95% Exact CI	**0.1004, 0.3604**	**0.0993, 0.4228**	**0.1308, 0.3314**
Non-responder, n(%)	**34 (79.1%)**	**23 (76.7%)**	**57 (78.1%)**

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (BAT->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of the 1st MMB dose in the ET phase
For Continuing (MMB->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of randomization excluding RBC transfusion associated with clinically overt bleeding.
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

Table 2.4601: Analysis of RBC Transfusion Free Response
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)
Week 12 in ET Phase			
Subjects ongoing and not reaching week 12 in ET phase, n(%)	0	0	0
Subjects included for Transfusion free response rate calculation, n(%)	43 (100.0%)	30 (100.0%)	73 (100.0%)
RBC Transfusion Free Rate at Week 12 in ET Phase			
Responder, n(%)	23 (53.5%)	13 (43.3%)	36 (49.3%)
95% Exact CI	0.3765, 0.6882	0.2546, 0.6257	0.3740, 0.6128
Non-responder, n(%)	20 (46.5%)	17 (56.7%)	37 (50.7%)
RBC Transfusion within 12 weeks prior to week 12 in ET phase	17 (39.5%)	8 (26.7%)	25 (34.2%)
Discontinued prior to week 12	3 (7.0%)	9 (30.0%)	12 (16.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (BAT->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of the 1st MMB dose in the ET phase
For Continuing (MMB->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of randomization excluding RBC transfusion associated with clinically overt bleeding.
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-rbc-tfr-et.sas V.03.05 Output file: t-rbc-tfr-et.pdf 24AUG2023:16:54

Table 2.4601: Analysis of RBC Transfusion Free Response
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)
Week 24 in ET Phase			
Subjects ongoing and not reaching week 24 in ET phase, n(%)	0	0	0
Subjects included for Transfusion free response rate calculation, n(%)	43 (100.0%)	30 (100.0%)	73 (100.0%)
RBC Transfusion Free Rate at Week 24 in ET Phase			
Responder, n(%)	20 (46.5%)	12 (40.0%)	32 (43.8%)
95% Exact CI	0.3118, 0.6235	0.2266, 0.5940	0.3224, 0.5595
Non-responder, n(%)	23 (53.5%)	18 (60.0%)	41 (56.2%)
RBC Transfusion within 12 weeks prior to week 24 in ET phase	14 (32.6%)	5 (16.7%)	19 (26.0%)
Discontinued prior to week 24	9 (20.9%)	13 (43.3%)	22 (30.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (BAT->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of the 1st MMB dose in the ET phase
For Continuing (MMB->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of randomization excluding RBC transfusion associated with clinically overt bleeding.
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-rbc-tfr-et.sas V.03.05 Output file: t-rbc-tfr-et.pdf 24AUG2023:16:54

Table 2.4601: Analysis of RBC Transfusion Free Response
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)
Week 36 in ET Phase			
Subjects ongoing and not reaching week 36 in ET phase, n(%)	0	0	0
Subjects included for Transfusion free response rate calculation, n(%)	43 (100.0%)	30 (100.0%)	73 (100.0%)
RBC Transfusion Free Rate at Week 36 in ET Phase			
Responder, n(%)	14 (32.6%)	9 (30.0%)	23 (31.5%)
95% Exact CI	0.1908, 0.4854	0.1473, 0.4940	0.2113, 0.4344
Non-responder, n(%)	29 (67.4%)	21 (70.0%)	50 (68.5%)
RBC Transfusion within 12 weeks prior to week 36 in ET phase	15 (34.9%)	7 (23.3%)	22 (30.1%)
Discontinued prior to week 36	14 (32.6%)	14 (46.7%)	28 (38.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (BAT->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of the 1st MMB dose in the ET phase
For Continuing (MMB->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of randomization excluding RBC transfusion associated with clinically overt bleeding.
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

Table 2.4601: Analysis of RBC Transfusion Free Response
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)
Week 48 in ET Phase			
Subjects ongoing and not reaching week 48 in ET phase, n(%)	0	0	0
Subjects included for Transfusion free response rate calculation, n(%)	43 (100.0%)	30 (100.0%)	73 (100.0%)
RBC Transfusion Free Rate at Week 48 in ET Phase			
Responder, n(%)	10 (23.3%)	12 (40.0%)	22 (30.1%)
95% Exact CI	0.1176, 0.3863	0.2266, 0.5940	0.1994, 0.4200
Non-responder, n(%)	33 (76.7%)	18 (60.0%)	51 (69.9%)
RBC Transfusion within 12 weeks prior to week 48 in ET phase	15 (34.9%)	4 (13.3%)	19 (26.0%)
Discontinued prior to week 48	18 (41.9%)	14 (46.7%)	32 (43.8%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (BAT->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of the 1st MMB dose in the ET phase
For Continuing (MMB->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of randomization excluding RBC transfusion associated with clinically overt bleeding.
RBC = Red Blood Cell

Table 2.4601: Analysis of RBC Transfusion Free Response
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)
Week 60 in ET Phase			
Subjects ongoing and not reaching week 60 in ET phase, n(%)	0	0	0
Subjects included for Transfusion free response rate calculation, n(%)	43 (100.0%)	30 (100.0%)	73 (100.0%)
RBC Transfusion Free Rate at Week 60 in ET Phase			
Responder, n(%)	10 (23.3%)	9 (30.0%)	19 (26.0%)
95% Exact CI	0.1176, 0.3863	0.1473, 0.4940	0.1645, 0.3762
Non-responder, n(%)	33 (76.7%)	21 (70.0%)	54 (74.0%)
RBC Transfusion within 12 weeks prior to week 60 in ET phase	10 (23.3%)	6 (20.0%)	16 (21.9%)
Discontinued prior to week 60	23 (53.5%)	15 (50.0%)	38 (52.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (BAT->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of the 1st MMB dose in the ET phase
For Continuing (MMB->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of randomization excluding RBC transfusion associated with clinically overt bleeding.
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

Table 2.4601: Analysis of RBC Transfusion Free Response
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)
Week 72 in ET Phase			
Subjects ongoing and not reaching week 72 in ET phase, n(%)	0	0	0
Subjects included for Transfusion free response rate calculation, n(%)	43 (100.0%)	30 (100.0%)	73 (100.0%)
RBC Transfusion Free Rate at Week 72 in ET Phase			
Responder, n(%)	11 (25.6%)	10 (33.3%)	21 (28.8%)
95% Exact CI	0.1352, 0.4117	0.1729, 0.5281	0.1877, 0.4055
Non-responder, n(%)	32 (74.4%)	20 (66.7%)	52 (71.2%)
RBC Transfusion within 12 weeks prior to week 72 in ET phase	6 (14.0%)	3 (10.0%)	9 (12.3%)
Discontinued prior to week 72	26 (60.5%)	17 (56.7%)	43 (58.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (BAT->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of the 1st MMB dose in the ET phase
For Continuing (MMB->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of randomization excluding RBC transfusion associated with clinically overt bleeding.
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

Table 2.4601: Analysis of RBC Transfusion Free Response
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)
Week 84 in ET Phase			
Subjects ongoing and not reaching week 84 in ET phase, n(%)	0	0	0
Subjects included for Transfusion free response rate calculation, n(%)	43 (100.0%)	30 (100.0%)	73 (100.0%)
RBC Transfusion Free Rate at Week 84 in ET Phase			
Responder, n(%)	9 (20.9%)	8 (26.7%)	17 (23.3%)
95% Exact CI	0.1004, 0.3604	0.1228, 0.4589	0.1419, 0.3465
Non-responder, n(%)	34 (79.1%)	22 (73.3%)	56 (76.7%)
RBC Transfusion within 12 weeks prior to week 84 in ET phase	5 (11.6%)	2 (6.7%)	7 (9.6%)
Discontinued prior to week 84	29 (67.4%)	20 (66.7%)	49 (67.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (BAT->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of the 1st MMB dose in the ET phase
For Continuing (MMB->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of randomization excluding RBC transfusion associated with clinically overt bleeding.
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-rbc-tfr-et.sas V.03.05 Output file: t-rbc-tfr-et.pdf 24AUG2023:16:54

Table 2.4601: Analysis of RBC Transfusion Free Response
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)
Week 96 in ET Phase			
Subjects ongoing and not reaching week 96 in ET phase, n(%)	0	0	0
Subjects included for Transfusion free response rate calculation, n(%)	43 (100.0%)	30 (100.0%)	73 (100.0%)
RBC Transfusion Free Rate at Week 96 in ET Phase			
Responder, n(%)	8 (18.6%)	6 (20.0%)	14 (19.2%)
95% Exact CI	0.0839, 0.3340	0.0771, 0.3857	0.1090, 0.3008
Non-responder, n(%)	35 (81.4%)	24 (80.0%)	59 (80.8%)
RBC Transfusion within 12 weeks prior to week 96 in ET phase	5 (11.6%)	4 (13.3%)	9 (12.3%)
Discontinued prior to week 96	30 (69.8%)	20 (66.7%)	50 (68.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (BAT->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of the 1st MMB dose in the ET phase
For Continuing (MMB->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of randomization excluding RBC transfusion associated with clinically overt bleeding.
RBC = Red Blood Cell

Table 2.4601: Analysis of RBC Transfusion Free Response
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)
Week 108 in ET Phase			
Subjects ongoing and not reaching week 108 in ET phase, n(%)	0	0	0
Subjects included for Transfusion free response rate calculation, n(%)	43 (100.0%)	30 (100.0%)	73 (100.0%)
RBC Transfusion Free Rate at Week 108 in ET Phase			
Responder, n(%)	6 (14.0%)	7 (23.3%)	13 (17.8%)
95% Exact CI	0.0530, 0.2793	0.0993, 0.4228	0.0984, 0.2853
Non-responder, n(%)	37 (86.0%)	23 (76.7%)	60 (82.2%)
RBC Transfusion within 12 weeks prior to week 108 in ET phase	5 (11.6%)	2 (6.7%)	7 (9.6%)
Discontinued prior to week 108	32 (74.4%)	21 (70.0%)	53 (72.6%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (BAT->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of the 1st MMB dose in the ET phase
For Continuing (MMB->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of randomization excluding RBC transfusion associated with clinically overt bleeding.
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

Table 2.4601: Analysis of RBC Transfusion Free Response
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)
Week 120 in ET Phase			
Subjects ongoing and not reaching week 120 in ET phase, n(%)	0	0	0
Subjects included for Transfusion free response rate calculation, n(%)	43 (100.0%)	30 (100.0%)	73 (100.0%)
RBC Transfusion Free Rate at Week 120 in ET Phase			
Responder, n(%)	5 (11.6%)	6 (20.0%)	11 (15.1%)
95% Exact CI	0.0389, 0.2508	0.0771, 0.3857	0.0777, 0.2536
Non-responder, n(%)	38 (88.4%)	24 (80.0%)	62 (84.9%)
RBC Transfusion within 12 weeks prior to week 120 in ET phase	4 (9.3%)	1 (3.3%)	5 (6.8%)
Discontinued prior to week 120	34 (79.1%)	23 (76.7%)	57 (78.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (BAT->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of the 1st MMB dose in the ET phase
For Continuing (MMB->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of randomization excluding RBC transfusion associated with clinically overt bleeding.
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

Table 2.4601: Analysis of RBC Transfusion Free Response
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)
Week 132 in ET Phase			
Subjects ongoing and not reaching week 132 in ET phase, n(%)	0	0	0
Subjects included for Transfusion free response rate calculation, n(%)	43 (100.0%)	30 (100.0%)	73 (100.0%)
RBC Transfusion Free Rate at Week 132 in ET Phase			
Responder, n(%)	4 (9.3%)	5 (16.7%)	9 (12.3%)
95% Exact CI	0.0259, 0.2214	0.0564, 0.3472	0.0580, 0.2212
Non-responder, n(%)	39 (90.7%)	25 (83.3%)	64 (87.7%)
RBC Transfusion within 12 weeks prior to week 132 in ET phase	3 (7.0%)	0	3 (4.1%)
Discontinued prior to week 132	36 (83.7%)	25 (83.3%)	61 (83.6%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (BAT->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of the 1st MMB dose in the ET phase
For Continuing (MMB->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of randomization excluding RBC transfusion associated with clinically overt bleeding.
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

Table 2.4601: Analysis of RBC Transfusion Free Response
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)
Week 144 in ET Phase			
Subjects ongoing and not reaching week 144 in ET phase, n(%)	0	0	0
Subjects included for Transfusion free response rate calculation, n(%)	43 (100.0%)	30 (100.0%)	73 (100.0%)
RBC Transfusion Free Rate at Week 144 in ET Phase			
Responder, n(%)	1 (2.3%)	3 (10.0%)	4 (5.5%)
95% Exact CI	0.0006, 0.1229	0.0211, 0.2653	0.0151, 0.1344
Non-responder, n(%)	42 (97.7%)	27 (90.0%)	69 (94.5%)
RBC Transfusion within 12 weeks prior to week 144 in ET phase	1 (2.3%)	0	1 (1.4%)
Discontinued prior to week 144	41 (95.3%)	27 (90.0%)	68 (93.2%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (BAT->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of the 1st MMB dose in the ET phase
For Continuing (MMB->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of randomization excluding RBC transfusion associated with clinically overt bleeding.
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

Table 2.4601: Analysis of RBC Transfusion Free Response
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)
Week 156 in ET Phase			
Subjects ongoing and not reaching week 156 in ET phase, n(%)	0	0	0
Subjects included for Transfusion free response rate calculation, n(%)	43 (100.0%)	30 (100.0%)	73 (100.0%)
RBC Transfusion Free Rate at Week 156 in ET Phase			
Responder, n(%)	2 (4.7%)	1 (3.3%)	3 (4.1%)
95% Exact CI	0.0057, 0.1581	0.0008, 0.1722	0.0086, 0.1154
Non-responder, n(%)	41 (95.3%)	29 (96.7%)	70 (95.9%)
RBC Transfusion within 12 weeks prior to week 156 in ET phase	0	0	0
Discontinued prior to week 156	41 (95.3%)	29 (96.7%)	70 (95.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For Switch (BAT->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of the 1st MMB dose in the ET phase
For Continuing (MMB->MMB) group, the baseline is based on the RBC transfusion with 84 days prior to or on the date of randomization excluding RBC transfusion associated with clinically overt bleeding.
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

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Table 2.4801: Analysis of Rate of RBC Transfusion Free Response by Week 24
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
RBC Transfusion Free Rate by Week 24 in RT Phase			
Responder, n(%)	28 (42.4%)	12 (30.8%)	40 (38.1%)
Unadjusted Inverse Relative Risk (95% CI)	0.73 (0.42, 1.25)		
p-value [1]	0.25		
Unadjusted Inverse Odds Ratio (95% CI)	0.60 (0.26, 1.39)		
p-value [1]	0.24		
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.07, 0.30)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.65 (0.41, 1.04)		
p-value [2]	0.075		
Subjects not Transfusion Free at Baseline, n	53	30	83
New RBC Transfusion Free Rate by Week 24			
Responder, n/N(%)	15/53 (28.3%)	3/30 (10.0%)	18/83 (21.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-rbc-tfr-rt-gba.sas V.03.05 Output file: t-rbc-tfr-rt-gba.pdf 24AUG2023:16:44

Table 2.5302: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Any Type Transfusion Free Rate at Week 24					
Responder, n(%)	5 (20.8%)	1 (11.1%)	6 (14.3%)	3 (10.0%)	
95% Exact CI	0.0713, 0.4215	0.0028, 0.4825	0.0543, 0.2854	0.0211, 0.2653	
Proportion Difference - Stratified CMH Method (95% CI)	0.04 (-0.30, 0.39)		0.09 (-0.08, 0.26)		
p-value	0.80		0.31		
Proportion Difference - Unstratified CMH Method (95% CI)	0.10 (-0.20, 0.40)		0.04 (-0.12, 0.20)		
p-value	0.53		0.60		
Proportion Difference - Unstratified Exact Method (95% CI)	0.10 (-0.29, 0.46)		0.04 (-0.19, 0.27)		
p-value	1.00		0.73		
Unadjusted Inverse Relative Risk (95% CI)	0.53 (0.07, 3.96)		0.70 (0.19, 2.58)		
p-value [1]	0.54		0.59		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.48 (0.05, 4.74)		0.67 (0.15, 2.91)		
p-value [1]	0.53		0.59		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.16, 0.36)		0.04 (-0.11, 0.19)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.5302: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Non-responder, n(%)	19 (79.2%)	8 (88.9%)	36 (85.7%)	27 (90.0%)	
Any Type Transfusion within 12 weeks prior to Week 24	11 (45.8%)	5 (55.6%)	26 (61.9%)	23 (76.7%)	
Discontinued prior to week 24	8 (33.3%)	3 (33.3%)	10 (23.8%)	4 (13.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.5307: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8g/dL		HGB >=8g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Any Type Transfusion Free Rate at Week 24					
Responder, n(%)	1 (3.7%)	0	10 (25.6%)	4 (12.1%)	
95% Exact CI	0.0009, 0.1897	0.0000, 0.4593	0.1304, 0.4213	0.0340, 0.2820	
Proportion Difference - Stratified CMH Method (95% CI)	0.04 (-0.30, 0.39)		0.13 (-0.06, 0.32)		
p-value	0.80		0.17		
Proportion Difference - Unstratified CMH Method (95% CI)	0.04 (-0.20, 0.28)		0.14 (-0.05, 0.32)		
p-value	0.76		0.15		
Proportion Difference - Unstratified Exact Method (95% CI)	0.04 (-0.41, 0.48)		0.14 (-0.10, 0.36)		
p-value	1.00		0.23		
Unadjusted Inverse Relative Risk (95% CI)	1.33 (0.06, 29.35)		0.47 (0.16, 1.37)		
p-value [1]	0.86		0.17		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Unadjusted Inverse Odds Ratio (95% CI)	1.36 (0.05, 37.35)		0.40 (0.11, 1.42)		
p-value [1]	0.86		0.16		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.23, 0.19)		0.14 (-0.04, 0.31)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.48 (0.18, 1.29)		
p-value [2]	NE		0.15		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.5307: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8g/dL		HGB >=8g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Non-responder, n(%)	26 (96.3%)	6 (100.0%)	29 (74.4%)	29 (87.9%)	
Any Type Transfusion within 12 weeks prior to Week 24	18 (66.7%)	4 (66.7%)	19 (48.7%)	24 (72.7%)	
Discontinued prior to week 24	8 (29.6%)	2 (33.3%)	10 (25.6%)	5 (15.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.5306: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline DIPSS Two-Level Risk

Randomized Treatment Phase

ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Any Type Transfusion Free Rate at Week 24					
Responder, n(%)	7 (14.3%)	4 (12.9%)	4 (23.5%)	0	
95% Exact CI	0.0594, 0.2724	0.0363, 0.2983	0.0681, 0.4990	0.0000, 0.3694	
Proportion Difference - Stratified CMH Method (95% CI)	0.08 (-0.09, 0.25)		0.22 (-0.13, 0.57)		
p-value	0.38		0.21		
Proportion Difference - Unstratified CMH Method (95% CI)	0.01 (-0.15, 0.17)		0.24 (-0.04, 0.51)		
p-value	0.87		0.090		
Proportion Difference - Unstratified Exact Method (95% CI)	0.01 (-0.21, 0.23)		0.24 (-0.17, 0.60)		
p-value	1.00		0.27		
Unadjusted Inverse Relative Risk (95% CI)	0.90 (0.29, 2.83)		0.22 (0.01, 3.69)		
p-value [1]	0.86		0.29		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NE
Unadjusted Inverse Odds Ratio (95% CI)	0.89 (0.24, 3.33)		0.18 (0.01, 3.71)		
p-value [1]	0.86		0.26		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.14, 0.17)		0.19 (-0.06, 0.44)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.5306: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NE
Non-responder, n(%)	42 (85.7%)	27 (87.1%)	13 (76.5%)	8 (100.0%)	
Any Type Transfusion within 12 weeks prior to Week 24	30 (61.2%)	21 (67.7%)	7 (41.2%)	7 (87.5%)	
Discontinued prior to week 24	12 (24.5%)	6 (19.4%)	6 (35.3%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

GSK Oncology
Study GS-US-352-1214

Table 2.5305: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Any Type Transfusion Free Rate at Week 24				
Responder, n(%)	2 (40.0%)	0	5 (11.4%)	4 (16.7%)
95% Exact CI	0.0527, 0.8534	0.0000, 0.4096	0.0379, 0.2456	0.0474, 0.3738
Proportion Difference - Stratified CMH Method (95% CI)	0.00 (-0.65, 0.65)		0.02 (-0.19, 0.23)	
p-value	1.00		0.87	
Proportion Difference - Unstratified CMH Method (95% CI)	0.40 (-0.12, 0.92)		-0.05 (-0.24, 0.13)	
p-value	0.13		0.57	
Proportion Difference - Unstratified Exact Method (95% CI)	0.40 (-0.17, 0.85)		-0.05 (-0.30, 0.20)	
p-value	0.15		0.71	
Unadjusted Inverse Relative Risk (95% CI)	0.15 (0.01, 2.58)		1.47 (0.43, 4.95)	
p-value [1]	0.19		0.54	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.09 (0.00, 2.51)		1.56 (0.38, 6.46)	
p-value [1]	0.16		0.54	
Unadjusted Absolute Risk Difference (95% CI)	0.35 (-0.07, 0.78)		-0.05 (-0.23, 0.12)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-responder, n(%)	3 (60.0%)	7 (100.0%)	39 (88.6%)	20 (83.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.5305: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=17)	High Risk BAT (N=8)	p-value
Any Type Transfusion Free Rate at Week 24			
Responder, n(%)	4 (23.5%)	0	
95% Exact CI	0.0681, 0.4990	0.0000, 0.3694	
Proportion Difference - Stratified CMH Method (95% CI)	0.22 (-0.13, 0.57)		
p-value	0.21		
Proportion Difference - Unstratified CMH Method (95% CI)	0.24 (-0.04, 0.51)		
p-value	0.090		
Proportion Difference - Unstratified Exact Method (95% CI)	0.24 (-0.17, 0.60)		
p-value	0.27		
Unadjusted Inverse Relative Risk (95% CI)	0.22 (0.01, 3.69)		
p-value [1]	0.29		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	0.18 (0.01, 3.71)		
p-value [1]	0.26		
Unadjusted Absolute Risk Difference (95% CI)	0.19 (-0.06, 0.44)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Non-responder, n(%)	13 (76.5%)	8 (100.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Table 2.5305: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Any Type Transfusion within 12 weeks prior to Week 24	2 (40.0%)	6 (85.7%)	28 (63.6%)	15 (62.5%)
Discontinued prior to week 24	1 (20.0%)	1 (14.3%)	11 (25.0%)	5 (20.8%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Table 2.5305: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=17)	High Risk BAT (N=8)	p-value
Any Type Transfusion within 12 weeks prior to Week 24	7 (41.2%)	7 (87.5%)	
Discontinued prior to week 24	6 (35.3%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Table 2.5308: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Any Type Transfusion Free Rate at Week 24				
Responder, n(%)	8 (17.8%)	2 (8.7%)	2 (15.4%)	1 (12.5%)
95% Exact CI	0.0800, 0.3205	0.0107, 0.2804	0.0192, 0.4545	0.0032, 0.5265
Proportion Difference - Stratified CMH Method (95% CI)	0.09 (-0.10, 0.29)		0.01 (-0.37, 0.38)	
p-value	0.34		0.98	
Proportion Difference - Unstratified CMH Method (95% CI)	0.09 (-0.08, 0.26)		0.03 (-0.32, 0.38)	
p-value	0.30		0.87	
Proportion Difference - Unstratified Exact Method (95% CI)	0.09 (-0.16, 0.33)		0.03 (-0.40, 0.44)	
p-value	0.48		1.00	
Unadjusted Inverse Relative Risk (95% CI)	0.49 (0.11, 2.12)		0.81 (0.09, 7.58)	
p-value [1]	0.34		0.86	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.44 (0.09, 2.27)		0.79 (0.06, 10.38)	
p-value [1]	0.33		0.85	
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.07, 0.25)		0.03 (-0.27, 0.33)	
Adjusted Inverse Relative Risk (95% CI) [2]	0.48 (0.12, 1.84)		NE	
p-value [2]	0.28		NE	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.5308: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=8)	Post-PV Myelofibrosis BAT (N=8)	p-value
Any Type Transfusion Free Rate at Week 24			
Responder, n(%)	1 (12.5%)	1 (12.5%)	
95% Exact CI	0.0032, 0.5265	0.0032, 0.5265	
Proportion Difference - Stratified CMH Method (95% CI)	0.13 (-0.40, 0.66)		
p-value	0.62		
Proportion Difference - Unstratified CMH Method (95% CI)	0.00 (-0.39, 0.39)		
p-value	1.00		
Proportion Difference - Unstratified Exact Method (95% CI)	0.00 (-0.51, 0.51)		
p-value	1.00		
Unadjusted Inverse Relative Risk (95% CI)	1.00 (0.07, 13.37)		
p-value [1]	1.00		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.87
Unadjusted Inverse Odds Ratio (95% CI)	1.00 (0.05, 19.36)		
p-value [1]	1.00		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.32, 0.32)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.5308: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-responder, n(%)	37 (82.2%)	21 (91.3%)	11 (84.6%)	7 (87.5%)
Any Type Transfusion within 12 weeks prior to Week 24	25 (55.6%)	17 (73.9%)	7 (53.8%)	5 (62.5%)
Discontinued prior to week 24	12 (26.7%)	4 (17.4%)	4 (30.8%)	2 (25.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Table 2.5308: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=8)	Post-PV Myelofibrosis BAT (N=8)	p-value
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.93
Non-responder, n(%)	7 (87.5%)	7 (87.5%)	
Any Type Transfusion within 12 weeks prior to Week 24	5 (62.5%)	6 (75.0%)	
Discontinued prior to week 24	2 (25.0%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.5304: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Any Type Transfusion Free Rate at Week 24					
Responder, n(%)	7 (24.1%)	2 (28.6%)	4 (10.8%)	2 (6.3%)	
95% Exact CI	0.1030, 0.4354	0.0367, 0.7096	0.0303, 0.2542	0.0077, 0.2081	
Proportion Difference - Stratified CMH Method (95% CI)	0.02 (-0.39, 0.42)		0.06 (-0.10, 0.21)		
p-value	0.93		0.48		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.04 (-0.45, 0.36)		0.05 (-0.10, 0.19)		
p-value	0.83		0.53		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.04 (-0.46, 0.36)		0.05 (-0.19, 0.28)		
p-value	1.00		0.68		
Unadjusted Inverse Relative Risk (95% CI)	1.18 (0.31, 4.51)		0.58 (0.11, 2.95)		
p-value [1]	0.80		0.51		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	1.26 (0.20, 7.97)		0.55 (0.09, 3.22)		
p-value [1]	0.81		0.51		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.41, 0.32)		0.05 (-0.08, 0.18)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.5304: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Non-responder, n(%)	22 (75.9%)	5 (71.4%)	33 (89.2%)	30 (93.8%)	
Any Type Transfusion within 12 weeks prior to Week 24	16 (55.2%)	4 (57.1%)	21 (56.8%)	24 (75.0%)	
Discontinued prior to week 24	6 (20.7%)	1 (14.3%)	12 (32.4%)	6 (18.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.5303: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Any Type Transfusion Free Rate at Week 24					
Responder, n(%)	9 (17.3%)	1 (5.6%)	2 (14.3%)	3 (14.3%)	
95% Exact CI	0.0823, 0.3033	0.0014, 0.2729	0.0178, 0.4281	0.0305, 0.3634	
Proportion Difference - Stratified CMH Method (95% CI)	0.11 (-0.09, 0.31)		0.09 (-0.17, 0.36)		
p-value	0.29		0.49		
Proportion Difference - Unstratified CMH Method (95% CI)	0.12 (-0.05, 0.28)		0.00 (-0.26, 0.26)		
p-value	0.16		1.00		
Proportion Difference - Unstratified Exact Method (95% CI)	0.12 (-0.15, 0.38)		0.00 (-0.34, 0.34)		
p-value	0.43		1.00		
Unadjusted Inverse Relative Risk (95% CI)	0.32 (0.04, 2.36)		1.00 (0.19, 5.24)		
p-value [1]	0.26		1.00		
Unadjusted interaction test for Treatment*Gender [3]					0.35
Unadjusted Inverse Odds Ratio (95% CI)	0.28 (0.03, 2.39)		1.00 (0.14, 6.91)		
p-value [1]	0.25		1.00		
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.03, 0.27)		0.00 (-0.24, 0.24)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.34 (0.06, 2.06)		0.46 (0.09, 2.32)		
p-value [2]	0.24		0.34		
Adjusted interaction test for Treatment*Gender [3]					0.68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.5303: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Non-responder, n(%)	43 (82.7%)	17 (94.4%)	12 (85.7%)	18 (85.7%)	
Any Type Transfusion within 12 weeks prior to Week 24	29 (55.8%)	13 (72.2%)	8 (57.1%)	15 (71.4%)	
Discontinued prior to week 24	14 (26.9%)	4 (22.2%)	4 (28.6%)	3 (14.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Table 2.5310: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Any Type Transfusion Free Rate at Week 24					
Responder, n(%)	5 (17.9%)	3 (12.5%)	6 (15.8%)	1 (6.7%)	
95% Exact CI	0.0606, 0.3689	0.0266, 0.3236	0.0602, 0.3125	0.0017, 0.3195	
Proportion Difference - Stratified CMH Method (95% CI)	0.09 (-0.14, 0.32)		0.11 (-0.16, 0.38)		
p-value	0.45		0.43		
Proportion Difference - Unstratified CMH Method (95% CI)	0.05 (-0.15, 0.26)		0.09 (-0.10, 0.29)		
p-value	0.61		0.36		
Proportion Difference - Unstratified Exact Method (95% CI)	0.05 (-0.22, 0.32)		0.09 (-0.20, 0.38)		
p-value	0.71		0.66		
Unadjusted Inverse Relative Risk (95% CI)	0.70 (0.19, 2.63)		0.42 (0.06, 3.22)		
p-value [1]	0.60		0.41		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.66 (0.14, 3.09)		0.38 (0.04, 3.47)		
p-value [1]	0.60		0.39		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.14, 0.25)		0.09 (-0.08, 0.26)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.5310: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Non-responder, n(%)	23 (82.1%)	21 (87.5%)	32 (84.2%)	14 (93.3%)	
Any Type Transfusion within 12 weeks prior to Week 24	18 (64.3%)	19 (79.2%)	19 (50.0%)	9 (60.0%)	
Discontinued prior to week 24	5 (17.9%)	2 (8.3%)	13 (34.2%)	5 (33.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.5309: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Any Type Transfusion Free Rate at Week 24					
Responder, n(%)	8 (19.0%)	2 (10.0%)	3 (12.5%)	2 (10.5%)	
95% Exact CI	0.0860, 0.3412	0.0123, 0.3170	0.0266, 0.3236	0.0130, 0.3314	
Proportion Difference - Stratified CMH Method (95% CI)	0.13 (-0.05, 0.31)		0.04 (-0.17, 0.25)		
p-value	0.16		0.73		
Proportion Difference - Unstratified CMH Method (95% CI)	0.09 (-0.10, 0.28)		0.02 (-0.19, 0.23)		
p-value	0.35		0.85		
Proportion Difference - Unstratified Exact Method (95% CI)	0.09 (-0.18, 0.35)		0.02 (-0.27, 0.31)		
p-value	0.48		1.00		
Unadjusted Inverse Relative Risk (95% CI)	0.53 (0.12, 2.25)		0.84 (0.16, 4.54)		
p-value [1]	0.39		0.84		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.68
Unadjusted Inverse Odds Ratio (95% CI)	0.47 (0.09, 2.46)		0.82 (0.12, 5.51)		
p-value [1]	0.37		0.84		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.09, 0.27)		0.02 (-0.17, 0.21)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.41 (0.12, 1.44)		0.73 (0.16, 3.37)		
p-value [2]	0.16		0.68		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.64

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Table 2.5309: Analysis of Rate of Any Type Transfusion Free Response at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Non-responder, n(%)	34 (81.0%)	18 (90.0%)	21 (87.5%)	17 (89.5%)	
Any Type Transfusion within 12 weeks prior to Week 24	25 (59.5%)	15 (75.0%)	12 (50.0%)	13 (68.4%)	
Discontinued prior to week 24	9 (21.4%)	3 (15.0%)	9 (37.5%)	4 (21.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.5102: Analysis of Rate of Any Type Transfusion Free Response by Week 24 by Age

Randomized Treatment Phase

ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Any Type Transfusion Free Rate by Week 24 in RT Phase					
Responder, n(%)	10 (41.7%)	3 (33.3%)	10 (23.8%)	6 (20.0%)	
Unadjusted Inverse Relative Risk (95% CI)	0.80 (0.28, 2.26)		0.84 (0.34, 2.06)		
p-value [1]	0.67		0.70		
Unadjusted interaction test for Treatment*Age Group [3]					0.94
Unadjusted Inverse Odds Ratio (95% CI)	0.70 (0.14, 3.49)		0.80 (0.26, 2.51)		
p-value [1]	0.66		0.70		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.28, 0.45)		0.04 (-0.15, 0.23)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.77 (0.34, 1.73)		0.60 (0.29, 1.26)		
p-value [2]	0.53		0.18		
Adjusted interaction test for Treatment*Age Group [3]					0.67
Subjects not Transfusion Free at Baseline, n	15	6	38	24	
New Any Type Transfusion Free Rate by Week 24					
Responder, n/N(%)	1/15 (6.7%)	0	6/38 (15.8%)	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

For MMB and BAT group, the baseline is based on any type of transfusion within 84 days prior to or on the date of randomization.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.5107: Analysis of Rate of Any Type Transfusion Free Response by Week 24 by Baseline Hemoglobin Level

Randomized Treatment Phase

ITT-Anemic Analysis Set

	HGB <8g/dL		HGB >=8g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Any Type Transfusion Free Rate by Week 24 in RT Phase					
Responder, n(%)	5 (18.5%)	0	15 (38.5%)	9 (27.3%)	
Unadjusted Inverse Relative Risk (95% CI)	0.36 (0.02, 5.83)		0.71 (0.36, 1.41)		
p-value [1]	0.47		0.32		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Unadjusted Inverse Odds Ratio (95% CI)	0.31 (0.02, 6.47)		0.60 (0.22, 1.63)		
p-value [1]	0.45		0.32		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.12, 0.37)		0.11 (-0.10, 0.33)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.67 (0.37, 1.21)		
p-value [2]	NE		0.18		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Subjects not Transfusion Free at Baseline, n	23	6	30	24	
New Any Type Transfusion Free Rate by Week 24					
Responder, n/N(%)	1/23 (4.3%)	0	6/30 (20.0%)	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

For MMB and BAT group, the baseline is based on any type of transfusion within 84 days prior to or on the date of randomization.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

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Table 2.5106: Analysis of Rate of Any Type Transfusion Free Response by Week 24 by Baseline DIPSS Two-Level Risk

Randomized Treatment Phase

ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Any Type Transfusion Free Rate by Week 24 in RT Phase					
Responder, n(%)	15 (30.6%)	9 (29.0%)	5 (29.4%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.95 (0.47, 1.90)		0.18 (0.01, 2.94)		
p-value [1]	0.88		0.23		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NE
Unadjusted Inverse Odds Ratio (95% CI)	0.93 (0.35, 2.48)		0.13 (0.01, 2.75)		
p-value [1]	0.88		0.19		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.19, 0.22)		0.25 (-0.01, 0.51)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.62 (0.37, 1.05)		NE		
p-value [2]	0.074		NE		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NE
Subjects not Transfusion Free at Baseline, n	38	22	15	8	
New Any Type Transfusion Free Rate by Week 24					
Responder, n/N(%)	4/38 (10.5%)	0	3/15 (20.0%)	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

For MMB and BAT group, the baseline is based on any type of transfusion within 84 days prior to or on the date of randomization.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

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Table 2.5105: Analysis of Rate of Any Type Transfusion Free Response by Week 24 by Baseline DIPSS Three-Level Risk

Randomized Treatment Phase

ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Any Type Transfusion Free Rate by Week 24 in RT Phase				
Responder, n(%)	2 (40.0%)	0	13 (29.5%)	9 (37.5%)
Unadjusted Inverse Relative Risk (95% CI)	0.15 (0.01, 2.58)		1.27 (0.64, 2.53)	
p-value [1]	0.19		0.50	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.09 (0.00, 2.51)		1.43 (0.50, 4.09)	
p-value [1]	0.16		0.50	
Unadjusted Absolute Risk Difference (95% CI)	0.35 (-0.07, 0.78)		-0.08 (-0.32, 0.16)	
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.72 (0.41, 1.29)	
p-value [2]	NE		0.28	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Subjects not Transfusion Free at Baseline, n	3	7	35	15
New Any Type Transfusion Free Rate by Week 24				
Responder, n/N(%)	0	0	4/35 (11.4%)	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

For MMB and BAT group, the baseline is based on any type of transfusion within 84 days prior to or on the date of randomization.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.5105: Analysis of Rate of Any Type Transfusion Free Response by Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
(Continued)	MMB (N=17)	BAT (N=8)	p-value
Any Type Transfusion Free Rate by Week 24 in RT Phase			
Responder, n(%)	5 (29.4%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.18 (0.01, 2.94)		
p-value [1]	0.23		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NE
Unadjusted Inverse Odds Ratio (95% CI)	0.13 (0.01, 2.75)		
p-value [1]	0.19		
Unadjusted Absolute Risk Difference (95% CI)	0.25 (-0.01, 0.51)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NE
Subjects not Transfusion Free at Baseline, n	15	8	
New Any Type Transfusion Free Rate by Week 24			
Responder, n/N(%)	3/15 (20.0%)	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is based on any type of transfusion within 84 days prior to or on the date of randomization.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

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Table 2.5108: Analysis of Rate of Any Type Transfusion Free Response by Week 24 by Baseline MF Disease Status

Randomized Treatment Phase

ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Any Type Transfusion Free Rate by Week 24 in RT Phase				
Responder, n(%)	15 (33.3%)	5 (21.7%)	3 (23.1%)	2 (25.0%)
Unadjusted Inverse Relative Risk (95% CI)	0.65 (0.27, 1.57)		1.08 (0.23, 5.14)	
p-value [1]	0.34		0.92	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.56 (0.17, 1.79)		1.11 (0.14, 8.68)	
p-value [1]	0.32		0.92	
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.10, 0.33)		-0.02 (-0.40, 0.36)	
Adjusted Inverse Relative Risk (95% CI) [2]	0.59 (0.29, 1.18)		NE	
p-value [2]	0.14		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Subjects not Transfusion Free at Baseline, n	36	18	10	6
New Any Type Transfusion Free Rate by Week 24				
Responder, n/N(%)	6/36 (16.7%)	0	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

For MMB and BAT group, the baseline is based on any type of transfusion within 84 days prior to or on the date of randomization.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.5108: Analysis of Rate of Any Type Transfusion Free Response by Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=8)	Post-PV Myelofibrosis BAT (N=8)	p-value
Any Type Transfusion Free Rate by Week 24 in RT Phase			
Responder, n(%)	2 (25.0%)	2 (25.0%)	
Unadjusted Inverse Relative Risk (95% CI)	1.00 (0.18, 5.46)		
p-value [1]	1.00		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.82
Unadjusted Inverse Odds Ratio (95% CI)	1.00 (0.10, 9.61)		
p-value [1]	1.00		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.42, 0.42)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.92
Subjects not Transfusion Free at Baseline, n	7	6	
New Any Type Transfusion Free Rate by Week 24			
Responder, n/N(%)	1/7 (14.3%)	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is based on any type of transfusion within 84 days prior to or on the date of randomization.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

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Table 2.5104: Analysis of Rate of Any Type Transfusion Free Response by Week 24 by Region

Randomized Treatment Phase

ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Any Type Transfusion Free Rate by Week 24 in RT Phase					
Responder, n(%)	10 (34.5%)	2 (28.6%)	10 (27.0%)	7 (21.9%)	
Unadjusted Inverse Relative Risk (95% CI)	0.83 (0.23, 2.96)		0.81 (0.35, 1.88)		
p-value [1]	0.77		0.62		
Unadjusted interaction test for Treatment*Region [3]					0.98
Unadjusted Inverse Odds Ratio (95% CI)	0.76 (0.12, 4.64)		0.76 (0.25, 2.29)		
p-value [1]	0.77		0.62		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.32, 0.44)		0.05 (-0.15, 0.25)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.75 (0.28, 2.01)		0.67 (0.33, 1.34)		
p-value [2]	0.57		0.26		
Adjusted interaction test for Treatment*Region [3]					0.89
Subjects not Transfusion Free at Baseline, n	23	5	30	25	
New Any Type Transfusion Free Rate by Week 24					
Responder, n/N(%)	4/23 (17.4%)	0	3/30 (10.0%)	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

For MMB and BAT group, the baseline is based on any type of transfusion within 84 days prior to or on the date of randomization.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.5103: Analysis of Rate of Any Type Transfusion Free Response by Week 24 by Gender

Randomized Treatment Phase

ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Any Type Transfusion Free Rate by Week 24 in RT Phase					
Responder, n(%)	14 (26.9%)	4 (22.2%)	6 (42.9%)	5 (23.8%)	
Unadjusted Inverse Relative Risk (95% CI)	0.83 (0.31, 2.18)		0.56 (0.21, 1.47)		
p-value [1]	0.70		0.24		
Unadjusted interaction test for Treatment*Gender [3]					0.58
Unadjusted Inverse Odds Ratio (95% CI)	0.78 (0.22, 2.76)		0.42 (0.10, 1.79)		
p-value [1]	0.69		0.24		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.18, 0.27)		0.19 (-0.13, 0.51)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.81 (0.39, 1.69)		0.25 (0.10, 0.62)		
p-value [2]	0.58		0.003		
Adjusted interaction test for Treatment*Gender [3]					0.14
Subjects not Transfusion Free at Baseline, n	43	14	10	16	
New Any Type Transfusion Free Rate by Week 24					
Responder, n/N(%)	5/43 (11.6%)	0	2/10 (20.0%)	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

For MMB and BAT group, the baseline is based on any type of transfusion within 84 days prior to or on the date of randomization.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.5110: Analysis of Rate of Any Type Transfusion Free Response by Week 24 by Baseline Spleen Volume

Randomized Treatment Phase

ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Any Type Transfusion Free Rate by Week 24 in RT Phase					
Responder, n(%)	10 (35.7%)	5 (20.8%)	10 (26.3%)	4 (26.7%)	
Unadjusted Inverse Relative Risk (95% CI)	0.58 (0.23, 1.47)		1.01 (0.38, 2.74)		
p-value [1]	0.25		0.98		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.44
Unadjusted Inverse Odds Ratio (95% CI)	0.47 (0.14, 1.66)		1.02 (0.26, 3.94)		
p-value [1]	0.24		0.98		
Unadjusted Absolute Risk Difference (95% CI)	0.15 (-0.09, 0.39)		0.00 (-0.27, 0.26)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.53 (0.25, 1.15)		0.74 (0.31, 1.77)		
p-value [2]	0.11		0.50		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.66
Subjects not Transfusion Free at Baseline, n	20	19	33	11	
New Any Type Transfusion Free Rate by Week 24					
Responder, n/N(%)	2/20 (10.0%)	0	5/33 (15.2%)	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

For MMB and BAT group, the baseline is based on any type of transfusion within 84 days prior to or on the date of randomization.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.5109: Analysis of Rate of Any Type Transfusion Free Response by Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Any Type Transfusion Free Rate by Week 24 in RT Phase					
Responder, n(%)	13 (31.0%)	4 (20.0%)	7 (29.2%)	5 (26.3%)	
Unadjusted Inverse Relative Risk (95% CI)	0.65 (0.24, 1.73)		0.90 (0.34, 2.40)		
p-value [1]	0.39		0.84		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.63
Unadjusted Inverse Odds Ratio (95% CI)	0.56 (0.16, 2.00)		0.87 (0.23, 3.34)		
p-value [1]	0.37		0.84		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.11, 0.33)		0.03 (-0.24, 0.30)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.52 (0.24, 1.11)		0.75 (0.33, 1.70)		
p-value [2]	0.089		0.49		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.53
Subjects not Transfusion Free at Baseline, n	33	16	20	14	
New Any Type Transfusion Free Rate by Week 24					
Responder, n/N(%)	4/33 (12.1%)	0	3/20 (15.0%)	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is based on any type of transfusion within 84 days prior to or on the date of randomization.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-sg-at-tfr-rt-gba.sas V.03.05 Output file: t-sg-at-tfr-rt-gba-tss.pdf 24AUG2023:16:46

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Table 2.4802: Analysis of Rate of RBC Transfusion Free Response by Week 24 by Age

Randomized Treatment Phase

ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
RBC Transfusion Free Rate by Week 24 in RT Phase					
Responder, n(%)	12 (50.0%)	3 (33.3%)	16 (38.1%)	9 (30.0%)	
Unadjusted Inverse Relative Risk (95% CI)	0.67 (0.24, 1.82)		0.79 (0.40, 1.54)		
p-value [1]	0.43		0.48		
Unadjusted interaction test for Treatment*Age Group [3]					0.78
Unadjusted Inverse Odds Ratio (95% CI)	0.50 (0.10, 2.48)		0.70 (0.26, 1.89)		
p-value [1]	0.40		0.48		
Unadjusted Absolute Risk Difference (95% CI)	0.17 (-0.20, 0.53)		0.08 (-0.14, 0.30)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.68 (0.32, 1.47)		0.67 (0.36, 1.26)		
p-value [2]	0.33		0.22		
Adjusted interaction test for Treatment*Age Group [3]					0.81
Subjects not Transfusion Free at Baseline, n	15	6	38	24	
New RBC Transfusion Free Rate by Week 24					
Responder, n/N(%)	3/15 (20.0%)	0	12/38 (31.6%)	3/24 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.4807: Analysis of Rate of RBC Transfusion Free Response by Week 24 by Baseline Hemoglobin Level

Randomized Treatment Phase

ITT-Anemic Analysis Set

	HGB <8g/dL		HGB >=8g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
RBC Transfusion Free Rate by Week 24 in RT Phase					
Responder, n(%)	9 (33.3%)	0	19 (48.7%)	12 (36.4%)	
Unadjusted Inverse Relative Risk (95% CI)	0.21 (0.01, 3.20)		0.75 (0.43, 1.30)		
p-value [1]	0.26		0.30		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Unadjusted Inverse Odds Ratio (95% CI)	0.15 (0.01, 2.95)		0.60 (0.23, 1.55)		
p-value [1]	0.21		0.29		
Unadjusted Absolute Risk Difference (95% CI)	0.27 (0.01, 0.53)		0.12 (-0.10, 0.35)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.74 (0.45, 1.21)		
p-value [2]	NE		0.22		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Subjects not Transfusion Free at Baseline, n	23	6	30	24	
New RBC Transfusion Free Rate by Week 24					
Responder, n/N(%)	5/23 (21.7%)	0	10/30 (33.3%)	3/24 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.4806: Analysis of Rate of RBC Transfusion Free Response by Week 24 by Baseline DIPSS Two-Level Risk

Randomized Treatment Phase

ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
RBC Transfusion Free Rate by Week 24 in RT Phase					
Responder, n(%)	23 (46.9%)	12 (38.7%)	5 (29.4%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.82 (0.48, 1.41)		0.18 (0.01, 2.94)		
p-value [1]	0.48		0.23		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NE
Unadjusted Inverse Odds Ratio (95% CI)	0.71 (0.29, 1.78)		0.13 (0.01, 2.75)		
p-value [1]	0.47		0.19		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.14, 0.30)		0.25 (-0.01, 0.51)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.65 (0.41, 1.03)		NE		
p-value [2]	0.066		NE		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NE
Subjects not Transfusion Free at Baseline, n	38	22	15	8	
New RBC Transfusion Free Rate by Week 24					
Responder, n/N(%)	12/38 (31.6%)	3/22 (13.6%)	3/15 (20.0%)	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.4805: Analysis of Rate of RBC Transfusion Free Response by Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
RBC Transfusion Free Rate by Week 24 in RT Phase				
Responder, n(%)	2 (40.0%)	1 (14.3%)	21 (47.7%)	11 (45.8%)
Unadjusted Inverse Relative Risk (95% CI)	0.36 (0.04, 2.94)		0.96 (0.56, 1.64)	
p-value [1]	0.34		0.88	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.25 (0.02, 4.00)		0.93 (0.34, 2.51)	
p-value [1]	0.33		0.88	
Unadjusted Absolute Risk Difference (95% CI)	0.26 (-0.24, 0.76)		0.02 (-0.23, 0.27)	
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.66 (0.40, 1.10)	
p-value [2]	NE		0.11	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Subjects not Transfusion Free at Baseline, n	3	7	35	15
New RBC Transfusion Free Rate by Week 24				
Responder, n/N(%)	0	1/7 (14.3%)	12/35 (34.3%)	2/15 (13.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

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Table 2.4805: Analysis of Rate of RBC Transfusion Free Response by Week 24 by Baseline DIPSS Three-Level Risk

Randomized Treatment Phase

ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=17)	High Risk BAT (N=8)	p-value
RBC Transfusion Free Rate by Week 24 in RT Phase			
Responder, n(%)	5 (29.4%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.18 (0.01, 2.94)		
p-value [1]	0.23		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NE
Unadjusted Inverse Odds Ratio (95% CI)	0.13 (0.01, 2.75)		
p-value [1]	0.19		
Unadjusted Absolute Risk Difference (95% CI)	0.25 (-0.01, 0.51)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NE
Subjects not Transfusion Free at Baseline, n	15	8	
New RBC Transfusion Free Rate by Week 24			
Responder, n/N(%)	3/15 (20.0%)	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.4808: Analysis of Rate of RBC Transfusion Free Response by Week 24 by Baseline MF Disease Status

Randomized Treatment Phase

ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
RBC Transfusion Free Rate by Week 24 in RT Phase				
Responder, n(%)	19 (42.2%)	7 (30.4%)	5 (38.5%)	3 (37.5%)
Unadjusted Inverse Relative Risk (95% CI)	0.72 (0.36, 1.46)		0.98 (0.32, 3.01)	
p-value [1]	0.36		0.96	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.60 (0.21, 1.74)		0.96 (0.16, 5.90)	
p-value [1]	0.35		0.96	
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.12, 0.35)		0.01 (-0.42, 0.44)	
Adjusted Inverse Relative Risk (95% CI) [2]	0.69 (0.40, 1.22)		1.01 (0.29, 3.55)	
p-value [2]	0.20		0.99	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Subjects not Transfusion Free at Baseline, n	36	18	10	6
New RBC Transfusion Free Rate by Week 24				
Responder, n/N(%)	10/36 (27.8%)	2/18 (11.1%)	2/10 (20.0%)	1/6 (16.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.4808: Analysis of Rate of RBC Transfusion Free Response by Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=8)	Post-PV Myelofibrosis BAT (N=8)	p-value
RBC Transfusion Free Rate by Week 24 in RT Phase			
Responder, n(%)	4 (50.0%)	2 (25.0%)	
Unadjusted Inverse Relative Risk (95% CI)	0.50 (0.13, 2.00)		
p-value [1]	0.33		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.76
Unadjusted Inverse Odds Ratio (95% CI)	0.33 (0.04, 2.77)		
p-value [1]	0.31		
Unadjusted Absolute Risk Difference (95% CI)	0.25 (-0.21, 0.71)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.38
Subjects not Transfusion Free at Baseline, n	7	6	
New RBC Transfusion Free Rate by Week 24			
Responder, n/N(%)	3/7 (42.9%)	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

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Table 2.4804: Analysis of Rate of RBC Transfusion Free Response by Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
RBC Transfusion Free Rate by Week 24 in RT Phase					
Responder, n(%)	13 (44.8%)	2 (28.6%)	15 (40.5%)	10 (31.3%)	
Unadjusted Inverse Relative Risk (95% CI)	0.64 (0.18, 2.20)		0.77 (0.40, 1.47)		
p-value [1]	0.48		0.43		
Unadjusted interaction test for Treatment*Region [3]					0.78
Unadjusted Inverse Odds Ratio (95% CI)	0.49 (0.08, 2.97)		0.67 (0.25, 1.80)		
p-value [1]	0.44		0.42		
Unadjusted Absolute Risk Difference (95% CI)	0.16 (-0.22, 0.54)		0.09 (-0.13, 0.32)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.61 (0.22, 1.68)		0.70 (0.40, 1.24)		
p-value [2]	0.34		0.22		
Adjusted interaction test for Treatment*Region [3]					0.87
Subjects not Transfusion Free at Baseline, n	23	5	30	25	
New RBC Transfusion Free Rate by Week 24					
Responder, n/N(%)	7/23 (30.4%)	0	8/30 (26.7%)	3/25 (12.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.4803: Analysis of Rate of RBC Transfusion Free Response by Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
RBC Transfusion Free Rate by Week 24 in RT Phase					
Responder, n(%)	19 (36.5%)	5 (27.8%)	9 (64.3%)	7 (33.3%)	
Unadjusted Inverse Relative Risk (95% CI)	0.76 (0.33, 1.74)		0.52 (0.25, 1.07)		
p-value [1]	0.52		0.074		
Unadjusted interaction test for Treatment*Gender [3]					0.51
Unadjusted Inverse Odds Ratio (95% CI)	0.67 (0.21, 2.16)		0.28 (0.07, 1.15)		
p-value [1]	0.50		0.077		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.16, 0.33)		0.31 (-0.01, 0.63)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.76 (0.39, 1.51)		0.29 (0.12, 0.70)		
p-value [2]	0.44		0.006		
Adjusted interaction test for Treatment*Gender [3]					0.14
Subjects not Transfusion Free at Baseline, n	43	14	10	16	
New RBC Transfusion Free Rate by Week 24					
Responder, n/N(%)	10/43 (23.3%)	1/14 (7.1%)	5/10 (50.0%)	2/16 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.4810: Analysis of Rate of RBC Transfusion Free Response by Week 24 by Baseline Spleen Volume

Randomized Treatment Phase

ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
RBC Transfusion Free Rate by Week 24 in RT Phase					
Responder, n(%)	16 (57.1%)	5 (20.8%)	12 (31.6%)	7 (46.7%)	
Unadjusted Inverse Relative Risk (95% CI)	0.36 (0.16, 0.85)		1.48 (0.72, 3.02)		
p-value [1]	0.019		0.28		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.020
Unadjusted Inverse Odds Ratio (95% CI)	0.20 (0.06, 0.68)		1.90 (0.56, 6.44)		
p-value [1]	0.010		0.31		
Unadjusted Absolute Risk Difference (95% CI)	0.36 (0.12, 0.61)		-0.15 (-0.44, 0.14)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.33 (0.17, 0.67)		1.45 (0.74, 2.86)		
p-value [2]	0.002		0.28		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.012
Subjects not Transfusion Free at Baseline, n	20	19	33	11	
New RBC Transfusion Free Rate by Week 24					
Responder, n/N(%)	8/20 (40.0%)	0	7/33 (21.2%)	3/11 (27.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.4809: Analysis of Rate of RBC Transfusion Free Response by Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
RBC Transfusion Free Rate by Week 24 in RT Phase					
Responder, n(%)	21 (50.0%)	6 (30.0%)	7 (29.2%)	6 (31.6%)	
Unadjusted Inverse Relative Risk (95% CI)	0.60 (0.29, 1.25)		1.08 (0.44, 2.69)		
p-value [1]	0.17		0.86		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.33
Unadjusted Inverse Odds Ratio (95% CI)	0.43 (0.14, 1.33)		1.12 (0.30, 4.15)		
p-value [1]	0.14		0.86		
Unadjusted Absolute Risk Difference (95% CI)	0.20 (-0.05, 0.45)		-0.02 (-0.30, 0.25)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.52 (0.28, 0.95)		0.93 (0.41, 2.12)		
p-value [2]	0.033		0.86		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.25
Subjects not Transfusion Free at Baseline, n	33	16	20	14	
New RBC Transfusion Free Rate by Week 24					
Responder, n/N(%)	12/33 (36.4%)	2/16 (12.5%)	3/20 (15.0%)	1/14 (7.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
For MMB and BAT group, the baseline is based on the RBC transfusion within 84 days prior to or on the date of randomization. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.5502: Analysis of Time to Any Type Transfusion Free Response by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Subjects with Event					
Any Type Transfusion Free Response, n(%)	9 (37.5%)	1 (11.1%)	18 (42.9%)	9 (30.0%)	
Censor					
Subjects Censored, n(%)	15 (62.5%)	8 (88.9%)	24 (57.1%)	21 (70.0%)	
Kaplan-Meier Estimate of Time to Any Type Transfusion Free Response (Weeks)					
25-percentile (95% CI)	12.43 (12.14, 19.57)	NE (12.14, NE)	12.57 (12.14, 17.86)	18.14 (12.14, NE)	
Median (95% CI)	NE (12.43, NE)	NE (12.14, NE)	22.43 (14.00, NE)	NE (18.57, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	4.14, 26.29	2.86, 24.57	4.00, 26.43	1.86, 25.29	
Stratified Log-Rank Test p-value	0.32		0.073		
Adjusted Inverse Hazard Ratio (95% CI)	0.40 (0.05, 3.27)		0.45 (0.19, 1.09)		
Unstratified Log-Rank Test p-value	0.26		0.15		
Unadjusted Inverse Hazard Ratio (95% CI)	0.33 (0.04, 2.65)		0.56 (0.25, 1.25)		
P-value for interaction test					0.93

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusion of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-any-tfr-sub.sas V.03.05 Output file: t-tte-any-tfr-age.pdf 24AUG2023:16:40

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Table 2.5506: Analysis of Time to Any Type Transfusion Free Response by Baseline DIPSS Two-Level Risk

Randomized Treatment Phase

ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Subjects with Event					
Any Type Transfusion Free Response, n(%)	21 (42.9%)	9 (29.0%)	6 (35.3%)	1 (12.5%)	
Censor					
Subjects Censored, n(%)	28 (57.1%)	22 (71.0%)	11 (64.7%)	7 (87.5%)	
Kaplan-Meier Estimate of Time to Any Type Transfusion Free Response (Weeks)					
25-percentile (95% CI)	13.29 (12.14, 19.29)	16.57 (12.14, NE)	12.14 (12.14, NE)	NE (18.57, NE)	
Median (95% CI)	NE (17.86, NE)	NE (18.14, NE)	NE (12.14, NE)	NE (18.57, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	4.14, 26.43	2.86, 25.00	4.00, 25.00	1.86, 25.29	
Stratified Log-Rank Test p-value	0.097		0.11		
Adjusted Inverse Hazard Ratio (95% CI)	0.47 (0.20, 1.10)		0.21 (0.02, 1.85)		
Unstratified Log-Rank Test p-value	0.26		0.14		
Unadjusted Inverse Hazard Ratio (95% CI)	0.65 (0.30, 1.41)		0.23 (0.03, 1.94)		
P-value for interaction test					0.60

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Any type transfusion free response is defined as the absence of transfusion of any type in the prior 12 weeks.

Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).

Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.

Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.

P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

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Table 2.5505: Analysis of Time to Any Type Transfusion Free Response by Baseline DIPSS Three-Level Risk

Randomized Treatment Phase

ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Subjects with Event				
Any Type Transfusion Free Response, n(%)	2 (40.0%)	1 (14.3%)	19 (43.2%)	8 (33.3%)
Censor				
Subjects Censored, n(%)	3 (60.0%)	6 (85.7%)	25 (56.8%)	16 (66.7%)
Kaplan-Meier Estimate of Time to Any Type Transfusion Free Response (Weeks)				
25-percentile (95% CI)	12.14 (12.14, NE)	NE (14.14, NE)	14.14 (12.14, 19.57)	14.64 (12.14, NE)
Median (95% CI)	NE (12.14, NE)	NE (14.14, NE)	22.43 (17.86, NE)	NE (12.71, NE)
75-percentile (95% CI)	NE (12.14, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Min, Max	9.29, 23.86	2.86, 24.14	4.14, 26.43	7.00, 25.00
Stratified Log-Rank Test p-value	0.41		0.25	
Adjusted Inverse Hazard Ratio (95% CI)	>999.99 (<0.01, NE)		0.56 (0.22, 1.45)	
Unstratified Log-Rank Test p-value	0.23		0.54	
Unadjusted Inverse Hazard Ratio (95% CI)	0.24 (0.02, 2.67)		0.78 (0.34, 1.80)	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Any type transfusion free response is defined as the absence of transfusion of any type in the prior 12 weeks.

Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).

Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.

Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.

P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.5505: Analysis of Time to Any Type Transfusion Free Response by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=17)	High Risk BAT (N=8)	p-value
Subjects with Event			
Any Type Transfusion Free Response, n(%)	6 (35.3%)	1 (12.5%)	
Censor			
Subjects Censored, n(%)	11 (64.7%)	7 (87.5%)	
Kaplan-Meier Estimate of Time to Any Type Transfusion Free Response (Weeks)			
25-percentile (95% CI)	12.14 (12.14, NE)	NE (18.57, NE)	
Median (95% CI)	NE (12.14, NE)	NE (18.57, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	
Min, Max	4.00, 25.00	1.86, 25.29	
Stratified Log-Rank Test p-value	0.11		
Adjusted Inverse Hazard Ratio (95% CI)	0.21 (0.02, 1.85)		
Unstratified Log-Rank Test p-value	0.14		
Unadjusted Inverse Hazard Ratio (95% CI)	0.23 (0.03, 1.94)		
P-value for interaction test			0.73

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusion of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

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Table 2.5504: Analysis of Time to Any Type Transfusion Free Response by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Subjects with Event					
Any Type Transfusion Free Response, n(%)	13 (44.8%)	2 (28.6%)	14 (37.8%)	8 (25.0%)	
Censor					
Subjects Censored, n(%)	16 (55.2%)	5 (71.4%)	23 (62.2%)	24 (75.0%)	
Kaplan-Meier Estimate of Time to Any Type Transfusion Free Response (Weeks)					
25-percentile (95% CI)	12.14 (12.14, 14.14)	12.14 (12.14, NE)	15.43 (12.14, 22.29)	18.57 (12.14, NE)	
Median (95% CI)	22.14 (12.29, NE)	NE (12.14, NE)	NE (17.86, NE)	NE (23.71, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (12.14, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	4.14, 25.00	1.86, 25.29	4.00, 26.43	2.86, 25.00	
Stratified Log-Rank Test p-value	0.22		0.14		
Adjusted Inverse Hazard Ratio (95% CI)	0.58 (0.13, 2.66)		0.46 (0.19, 1.14)		
Unstratified Log-Rank Test p-value	0.51		0.19		
Unadjusted Inverse Hazard Ratio (95% CI)	0.64 (0.14, 2.86)		0.56 (0.24, 1.34)		
P-value for interaction test					0.73

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusion of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-any-tfr-sub.sas V.03.05 Output file: t-tte-any-tfr-geo.pdf 24AUG2023:16:40

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Table 2.5507: Analysis of Time to Any Type Transfusion Free Response by Baseline Hemoglobin Level

Randomized Treatment Phase

ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Subjects with Event					
Any Type Transfusion Free Response, n(%)	10 (37.0%)	1 (16.7%)	17 (43.6%)	9 (27.3%)	
Censor					
Subjects Censored, n(%)	17 (63.0%)	5 (83.3%)	22 (56.4%)	24 (72.7%)	
Kaplan-Meier Estimate of Time to Any Type Transfusion Free Response (Weeks)					
25-percentile (95% CI)	14.00 (12.14, 22.14)	NE (18.57, NE)	12.14 (12.14, 19.29)	18.14 (12.14, NE)	
Median (95% CI)	NE (14.14, NE)	NE (18.57, NE)	22.43 (12.43, NE)	NE (23.71, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (18.57, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	4.00, 25.00	2.86, 25.29	4.14, 26.43	1.86, 25.00	
Stratified Log-Rank Test p-value	0.43		0.077		
Adjusted Inverse Hazard Ratio (95% CI)	0.44 (0.06, 3.50)		0.44 (0.19, 1.02)		
Unstratified Log-Rank Test p-value	0.43		0.11		
Unadjusted Inverse Hazard Ratio (95% CI)	0.44 (0.06, 3.47)		0.51 (0.23, 1.16)		
P-value for interaction test					0.92

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Any type transfusion free response is defined as the absence of transfusion of any type in the prior 12 weeks.

Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).

Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.

Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.

P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

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Table 2.5508: Analysis of Time to Any Type Transfusion Free Response by Baseline MF Disease Status

Randomized Treatment Phase

ITT-Anemic Analysis Set

	Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=13)	BAT (N=8)	MMB (N=8)	BAT (N=8)
Subjects with Event				
Any Type Transfusion Free Response, n(%)	5 (38.5%)	2 (25.0%)	3 (37.5%)	2 (25.0%)
Censor				
Subjects Censored, n(%)	8 (61.5%)	6 (75.0%)	5 (62.5%)	6 (75.0%)
Kaplan-Meier Estimate of Time to Any Type Transfusion Free Response (Weeks)				
25-percentile (95% CI)	12.29 (12.14, NE)	23.71 (12.14, NE)	18.29 (12.14, NE)	18.14 (12.14, NE)
Median (95% CI)	NE (12.14, NE)	NE (12.14, NE)	NE (12.14, NE)	NE (12.14, NE)
75-percentile (95% CI)	NE (22.14, NE)	NE (23.71, NE)	NE (22.43, NE)	NE (NE, NE)
Min, Max	4.00, 25.00	1.86, 25.00	12.14, 25.29	7.71, 24.57
Stratified Log-Rank Test p-value	0.50		0.18	
Adjusted Inverse Hazard Ratio (95% CI)	0.72 (0.11, 4.67)		<0.01 (<0.01, NE)	
Unstratified Log-Rank Test p-value	0.53		0.69	
Unadjusted Inverse Hazard Ratio (95% CI)	0.59 (0.11, 3.10)		0.70 (0.12, 4.20)	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Any type transfusion free response is defined as the absence of transfusion of any type in the prior 12 weeks.

Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).

Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.

Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.

P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.5508: Analysis of Time to Any Type Transfusion Free Response by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Primary Myelofibrosis MMB (N=45)	Primary Myelofibrosis BAT (N=23)	p-value
Subjects with Event			
Any Type Transfusion Free Response, n(%)	**19 (42.2%)**	**6 (26.1%)**	
Censor			
Subjects Censored, n(%)	**26 (57.8%)**	**17 (73.9%)**	
Kaplan-Meier Estimate of Time to Any Type Transfusion Free Response (Weeks)			
25-percentile (95% CI)	**12.50 (12.14, 17.14)**	**17.57 (12.14, NE)**	
Median (95% CI)	**22.29 (15.43, NE)**	**NE (16.57, NE)**	
75-percentile (95% CI)	**NE (NE, NE)**	**NE (NE, NE)**	
Min, Max	**4.14, 26.43**	**2.86, 25.29**	
Stratified Log-Rank Test p-value	**0.12**		
Adjusted Inverse Hazard Ratio (95% CI)	**0.46 (0.18, 1.18)**		
Unstratified Log-Rank Test p-value	**0.15**		
Unadjusted Inverse Hazard Ratio (95% CI)	**0.52 (0.21, 1.29)**		
P-value for interaction test			**0.91**

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusion of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

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Table 2.5503: Analysis of Time to Any Type Transfusion Free Response by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Subjects with Event					
Any Type Transfusion Free Response, n(%)	19 (36.5%)	4 (22.2%)	8 (57.1%)	6 (28.6%)	
Censor					
Subjects Censored, n(%)	33 (63.5%)	14 (77.8%)	6 (42.9%)	15 (71.4%)	
Kaplan-Meier Estimate of Time to Any Type Transfusion Free Response (Weeks)					
25-percentile (95% CI)	12.43 (12.14, 19.57)	18.57 (12.14, NE)	12.57 (12.14, 17.86)	18.14 (12.14, NE)	
Median (95% CI)	NE (19.29, NE)	NE (16.57, NE)	17.86 (12.29, NE)	NE (18.14, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (14.14, NE)	NE (NE, NE)	
Min, Max	4.00, 26.43	1.86, 25.29	6.86, 24.86	7.71, 25.00	
Stratified Log-Rank Test p-value	0.26		0.020		
Adjusted Inverse Hazard Ratio (95% CI)	0.51 (0.17, 1.51)		0.21 (0.05, 0.85)		
Unstratified Log-Rank Test p-value	0.32		0.051		
Unadjusted Inverse Hazard Ratio (95% CI)	0.58 (0.20, 1.70)		0.37 (0.12, 1.08)		
P-value for interaction test					0.34

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusion of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-any-tfr-sub.sas V.03.05 Output file: t-tte-any-tfr-sex.pdf 24AUG2023:16:40

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Table 2.5510: Analysis of Time to Any Type Transfusion Free Response by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Subjects with Event					
Any Type Transfusion Free Response, n(%)	17 (60.7%)	5 (20.8%)	10 (26.3%)	5 (33.3%)	
Censor					
Subjects Censored, n(%)	11 (39.3%)	19 (79.2%)	28 (73.7%)	10 (66.7%)	
Kaplan-Meier Estimate of Time to Any Type Transfusion Free Response (Weeks)					
25-percentile (95% CI)	12.43 (12.14, 14.14)	NE (12.14, NE)	14.71 (12.14, NE)	14.14 (12.14, NE)	
Median (95% CI)	19.29 (12.57, NE)	NE (NE, NE)	NE (19.57, NE)	NE (12.71, NE)	
75-percentile (95% CI)	NE (22.14, NE)	NE (NE, NE)	NE (NE, NE)	NE (23.71, NE)	
Min, Max	6.86, 25.29	1.86, 25.29	4.00, 26.43	2.86, 25.00	
Stratified Log-Rank Test p-value	0.004		0.85		
Adjusted Inverse Hazard Ratio (95% CI)	0.24 (0.08, 0.66)		0.96 (0.29, 3.13)		
Unstratified Log-Rank Test p-value	0.006		0.60		
Unadjusted Inverse Hazard Ratio (95% CI)	0.28 (0.10, 0.75)		1.27 (0.43, 3.72)		
P-value for interaction test					0.053

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusion of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-any-tfr-sub.sas V.03.05 Output file: t-tte-any-tfr-svb.pdf 24AUG2023:16:40

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Table 2.5509: Analysis of Time to Any Type Transfusion Free Response by Baseline TSS

Randomized Treatment Phase

ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Subjects with Event					
Any Type Transfusion Free Response, n(%)	19 (45.2%)	6 (30.0%)	8 (33.3%)	4 (21.1%)	
Censor					
Subjects Censored, n(%)	23 (54.8%)	14 (70.0%)	16 (66.7%)	15 (78.9%)	
Kaplan-Meier Estimate of Time to Any Type Transfusion Free Response (Weeks)					
25-percentile (95% CI)	12.29 (12.14, 17.86)	16.57 (12.14, NE)	13.21 (12.14, NE)	23.71 (12.14, NE)	
Median (95% CI)	22.43 (14.14, NE)	NE (16.57, NE)	NE (12.43, NE)	NE (18.57, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	4.14, 26.43	1.86, 25.29	4.00, 26.29	2.86, 24.57	
Stratified Log-Rank Test p-value	0.064		0.32		
Adjusted Inverse Hazard Ratio (95% CI)	0.38 (0.14, 1.00)		0.55 (0.17, 1.84)		
Unstratified Log-Rank Test p-value	0.22		0.32		
Unadjusted Inverse Hazard Ratio (95% CI)	0.57 (0.23, 1.43)		0.55 (0.17, 1.85)		
P-value for interaction test					0.87

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusion of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment and baseline TD (yes,no).
Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-any-tfr-sub.sas V.03.05 Output file: t-tte-any-tfr-tss.pdf 24AUG2023:16:40

Table 2.5501: Analysis of Time to Any Type Transfusion Free Response
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Subjects with Event		
Any Type Transfusion Free Response, n(%)	**27 (40.9%)**	**10 (25.6%)**
Censor		
Subjects Censored, n(%)	**39 (59.1%)**	**29 (74.4%)**
Kaplan-Meier Estimate of Time to Any Type Transfusion Free Response (Weeks)		
25-percentile (95% CI)	**12.43 (12.14, 17.14)**	**18.57 (12.14, NE)**
Median (95% CI)	**NE (17.14, NE)**	**NE (NE, NE)**
75-percentile (95% CI)	**NE (NE, NE)**	**NE (NE, NE)**
Min, Max	**4.00, 26.43**	**1.86, 25.29**
Stratified Log-Rank Test p-value	**0.037**	
Adjusted Inverse Hazard Ratio (95% CI)	**0.43 (0.20, 0.92)**	
Unstratified Log-Rank Test p-value	**0.092**	
Unadjusted Inverse Hazard Ratio (95% CI)	**0.54 (0.26, 1.12)**	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Any type transfusion free response is defined as the absence of transfusion of any type in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-any-tfr.sas V.03.05 Output file: t-tte-any-tfr.pdf 24AUG2023:16:38

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Table 2.5002: Analysis of Time to RBC Transfusion Free Response by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Subjects with Event					
RBC Transfusion Free Response, n(%)	9 (37.5%)	1 (11.1%)	18 (42.9%)	9 (30.0%)	
Censor					
Subjects Censored, n(%)	15 (62.5%)	8 (88.9%)	24 (57.1%)	21 (70.0%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Free Response (Weeks)					
25-percentile (95% CI)	12.43 (12.14, 19.57)	NE (12.14, NE)	12.29 (12.14, 17.86)	18.14 (12.14, NE)	
Median (95% CI)	NE (12.43, NE)	NE (12.14, NE)	22.43 (13.29, NE)	NE (18.57, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	4.14, 26.29	2.86, 24.57	4.00, 26.43	1.86, 25.29	
Stratified Log-Rank Test p-value	0.32		0.077		
Adjusted Inverse Hazard Ratio (95% CI)	0.40 (0.05, 3.27)		0.47 (0.20, 1.12)		
Unstratified Log-Rank Test p-value	0.26		0.16		
Unadjusted Inverse Hazard Ratio (95% CI)	0.33 (0.04, 2.65)		0.57 (0.26, 1.27)		
P-value for interaction test					0.90

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

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Table 2.5006: Analysis of Time to RBC Transfusion Free Response by Baseline DIPSS Two-Level Risk

Randomized Treatment Phase

ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Subjects with Event					
RBC Transfusion Free Response, n(%)	21 (42.9%)	9 (29.0%)	6 (35.3%)	1 (12.5%)	
Censor					
Subjects Censored, n(%)	28 (57.1%)	22 (71.0%)	11 (64.7%)	7 (87.5%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Free Response (Weeks)					
25-percentile (95% CI)	12.57 (12.14, 19.29)	16.57 (12.14, NE)	12.14 (12.14, NE)	NE (18.57, NE)	
Median (95% CI)	NE (17.86, NE)	NE (18.14, NE)	NE (12.14, NE)	NE (18.57, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	4.14, 26.43	2.86, 25.00	4.00, 25.00	1.86, 25.29	
Stratified Log-Rank Test p-value	0.10		0.11		
Adjusted Inverse Hazard Ratio (95% CI)	0.48 (0.21, 1.13)		0.21 (0.02, 1.85)		
Unstratified Log-Rank Test p-value	0.26		0.14		
Unadjusted Inverse Hazard Ratio (95% CI)	0.65 (0.30, 1.43)		0.23 (0.03, 1.94)		
P-value for interaction test					0.60

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.

Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).

Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.

Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.

P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

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Table 2.5005: Analysis of Time to RBC Transfusion Free Response by Baseline DIPSS Three-Level Risk

Randomized Treatment Phase

ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Subjects with Event				
RBC Transfusion Free Response, n(%)	2 (40.0%)	1 (14.3%)	19 (43.2%)	8 (33.3%)
Censor				
Subjects Censored, n(%)	3 (60.0%)	6 (85.7%)	25 (56.8%)	16 (66.7%)
Kaplan-Meier Estimate of Time to RBC Transfusion Free Response (Weeks)				
25-percentile (95% CI)	12.14 (12.14, NE)	NE (14.14, NE)	13.29 (12.14, 19.57)	14.36 (12.14, NE)
Median (95% CI)	NE (12.14, NE)	NE (14.14, NE)	22.43 (17.86, NE)	NE (12.14, NE)
75-percentile (95% CI)	NE (12.14, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Min, Max	9.29, 23.86	2.86, 24.14	4.14, 26.43	7.00, 25.00
Stratified Log-Rank Test p-value	0.41		0.26	
Adjusted Inverse Hazard Ratio (95% CI)	>999.99 (<0.01, NE)		0.58 (0.22, 1.48)	
Unstratified Log-Rank Test p-value	0.23		0.54	
Unadjusted Inverse Hazard Ratio (95% CI)	0.24 (0.02, 2.67)		0.79 (0.35, 1.82)	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.

Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).

Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.

Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.

P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.5005: Analysis of Time to RBC Transfusion Free Response by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=17)	High Risk BAT (N=8)	p-value
Subjects with Event			
RBC Transfusion Free Response, n(%)	6 (35.3%)	1 (12.5%)	
Censor			
Subjects Censored, n(%)	11 (64.7%)	7 (87.5%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Free Response (Weeks)			
25-percentile (95% CI)	12.14 (12.14, NE)	NE (18.57, NE)	
Median (95% CI)	NE (12.14, NE)	NE (18.57, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	
Min, Max	4.00, 25.00	1.86, 25.29	
Stratified Log-Rank Test p-value	0.11		
Adjusted Inverse Hazard Ratio (95% CI)	0.21 (0.02, 1.85)		
Unstratified Log-Rank Test p-value	0.14		
Unadjusted Inverse Hazard Ratio (95% CI)	0.23 (0.03, 1.94)		
P-value for interaction test			0.73

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

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Table 2.5004: Analysis of Time to RBC Transfusion Free Response by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Subjects with Event					
RBC Transfusion Free Response, n(%)	13 (44.8%)	2 (28.6%)	14 (37.8%)	8 (25.0%)	
Censor					
Subjects Censored, n(%)	16 (55.2%)	5 (71.4%)	23 (62.2%)	24 (75.0%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Free Response (Weeks)					
25-percentile (95% CI)	12.14 (12.14, 14.00)	12.14 (12.14, NE)	15.43 (12.14, 22.29)	18.57 (12.14, NE)	
Median (95% CI)	22.14 (12.14, NE)	NE (12.14, NE)	NE (17.86, NE)	NE (23.71, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (12.14, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	4.14, 25.00	1.86, 25.29	4.00, 26.43	2.86, 25.00	
Stratified Log-Rank Test p-value	0.22		0.14		
Adjusted Inverse Hazard Ratio (95% CI)	0.57 (0.12, 2.61)		0.48 (0.19, 1.17)		
Unstratified Log-Rank Test p-value	0.50		0.20		
Unadjusted Inverse Hazard Ratio (95% CI)	0.64 (0.14, 2.82)		0.57 (0.24, 1.37)		
P-value for interaction test					0.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-tfr-sub.sas V.03.05 Output file: t-tte-tfr-geo.pdf 24AUG2023:16:35

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Table 2.5007: Analysis of Time to RBC Transfusion Free Response by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Subjects with Event					
RBC Transfusion Free Response, n(%)	10 (37.0%)	1 (16.7%)	17 (43.6%)	9 (27.3%)	
Censor					
Subjects Censored, n(%)	17 (63.0%)	5 (83.3%)	22 (56.4%)	24 (72.7%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Free Response (Weeks)					
25-percentile (95% CI)	13.29 (12.14, 22.14)	NE (18.57, NE)	12.14 (12.14, 19.29)	18.14 (12.14, NE)	
Median (95% CI)	NE (14.00, NE)	NE (18.57, NE)	22.43 (12.43, NE)	NE (23.71, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (18.57, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	4.00, 25.00	2.86, 25.29	4.14, 26.43	1.86, 25.00	
Stratified Log-Rank Test p-value	0.43		0.079		
Adjusted Inverse Hazard Ratio (95% CI)	0.44 (0.06, 3.50)		0.45 (0.20, 1.05)		
Unstratified Log-Rank Test p-value	0.43		0.11		
Unadjusted Inverse Hazard Ratio (95% CI)	0.44 (0.06, 3.48)		0.52 (0.23, 1.18)		
P-value for interaction test					0.96

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-tfr-sub.sas V.03.05 Output file: t-tte-tfr-hgb.pdf 24AUG2023:16:35

Table 2.5008: Analysis of Time to RBC Transfusion Free Response by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=13)	BAT (N=8)	MMB (N=8)	BAT (N=8)
Subjects with Event				
RBC Transfusion Free Response, n(%)	5 (38.5%)	2 (25.0%)	3 (37.5%)	2 (25.0%)
Censor				
Subjects Censored, n(%)	8 (61.5%)	6 (75.0%)	5 (62.5%)	6 (75.0%)
Kaplan-Meier Estimate of Time to RBC Transfusion Free Response (Weeks)				
25-percentile (95% CI)	12.29 (12.14, NE)	23.71 (12.14, NE)	17.29 (12.14, NE)	18.14 (12.14, NE)
Median (95% CI)	NE (12.14, NE)	NE (12.14, NE)	NE (12.14, NE)	NE (12.14, NE)
75-percentile (95% CI)	NE (22.14, NE)	NE (23.71, NE)	NE (22.43, NE)	NE (NE, NE)
Min, Max	4.00, 25.00	1.86, 25.00	12.14, 25.29	7.71, 24.57
Stratified Log-Rank Test p-value	0.50		0.18	
Adjusted Inverse Hazard Ratio (95% CI)	0.72 (0.11, 4.67)		<0.01 (<0.01, NE)	
Unstratified Log-Rank Test p-value	0.53		0.68	
Unadjusted Inverse Hazard Ratio (95% CI)	0.59 (0.11, 3.10)		0.68 (0.11, 4.07)	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-tfr-sub.sas V.03.05 Output file: t-tte-tfr-mf.pdf 24AUG2023:16:35

Table 2.5008: Analysis of Time to RBC Transfusion Free Response by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Primary Myelofibrosis MMB (N=45)	Primary Myelofibrosis BAT (N=23)	p-value
Subjects with Event			
RBC Transfusion Free Response, n(%)	19 (42.2%)	6 (26.1%)	
Censor			
Subjects Censored, n(%)	26 (57.8%)	17 (73.9%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Free Response (Weeks)			
25-percentile (95% CI)	12.50 (12.14, 17.14)	17.57 (12.14, NE)	
Median (95% CI)	22.29 (15.43, NE)	NE (16.57, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	
Min, Max	4.14, 26.43	2.86, 25.29	
Stratified Log-Rank Test p-value	0.12		
Adjusted Inverse Hazard Ratio (95% CI)	0.49 (0.19, 1.23)		
Unstratified Log-Rank Test p-value	0.16		
Unadjusted Inverse Hazard Ratio (95% CI)	0.53 (0.21, 1.32)		
P-value for interaction test			0.87

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-tfr-sub.sas V.03.05 Output file: t-tte-tfr-mf.pdf 24AUG2023:16:35

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Table 2.5003: Analysis of Time to RBC Transfusion Free Response by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Subjects with Event					
RBC Transfusion Free Response, n(%)	19 (36.5%)	4 (22.2%)	8 (57.1%)	6 (28.6%)	
Censor					
Subjects Censored, n(%)	33 (63.5%)	14 (77.8%)	6 (42.9%)	15 (71.4%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Free Response (Weeks)					
25-percentile (95% CI)	12.43 (12.14, 19.57)	18.57 (12.14, NE)	12.29 (12.14, 17.86)	18.14 (12.14, NE)	
Median (95% CI)	NE (19.29, NE)	NE (16.57, NE)	17.86 (12.14, NE)	NE (18.14, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (13.29, NE)	NE (NE, NE)	
Min, Max	4.00, 26.43	1.86, 25.29	6.86, 24.86	7.71, 25.00	
Stratified Log-Rank Test p-value	0.26		0.020		
Adjusted Inverse Hazard Ratio (95% CI)	0.51 (0.17, 1.51)		0.21 (0.05, 0.85)		
Unstratified Log-Rank Test p-value	0.32		0.053		
Unadjusted Inverse Hazard Ratio (95% CI)	0.58 (0.20, 1.70)		0.38 (0.13, 1.11)		
P-value for interaction test					0.35

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-tfr-sub.sas V.03.05 Output file: t-tte-tfr-sex.pdf 24AUG2023:16:35

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Table 2.5010: Analysis of Time to RBC Transfusion Free Response by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Subjects with Event					
RBC Transfusion Free Response, n(%)	17 (60.7%)	5 (20.8%)	10 (26.3%)	5 (33.3%)	
Censor					
Subjects Censored, n(%)	11 (39.3%)	19 (79.2%)	28 (73.7%)	10 (66.7%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Free Response (Weeks)					
25-percentile (95% CI)	12.29 (12.14, 14.00)	NE (12.14, NE)	14.71 (12.14, NE)	14.14 (12.14, NE)	
Median (95% CI)	19.29 (12.43, NE)	NE (NE, NE)	NE (19.57, NE)	NE (12.14, NE)	
75-percentile (95% CI)	NE (22.14, NE)	NE (NE, NE)	NE (NE, NE)	NE (23.71, NE)	
Min, Max	6.86, 25.29	1.86, 25.29	4.00, 26.43	2.86, 25.00	
Stratified Log-Rank Test p-value	0.004		0.99		
Adjusted Inverse Hazard Ratio (95% CI)	0.24 (0.08, 0.66)		1.07 (0.33, 3.42)		
Unstratified Log-Rank Test p-value	0.006		0.57		
Unadjusted Inverse Hazard Ratio (95% CI)	0.27 (0.10, 0.75)		1.33 (0.45, 3.89)		
P-value for interaction test					0.037

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-tfr-sub.sas V.03.05 Output file: t-tte-tfr-svb.pdf 24AUG2023:16:35

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Table 2.5009: Analysis of Time to RBC Transfusion Free Response by Baseline TSS

Randomized Treatment Phase

ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Subjects with Event					
RBC Transfusion Free Response, n(%)	19 (45.2%)	6 (30.0%)	8 (33.3%)	4 (21.1%)	
Censor					
Subjects Censored, n(%)	23 (54.8%)	14 (70.0%)	16 (66.7%)	15 (78.9%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Free Response (Weeks)					
25-percentile (95% CI)	12.29 (12.14, 17.86)	16.57 (12.14, NE)	13.21 (12.14, NE)	23.71 (12.14, NE)	
Median (95% CI)	22.43 (13.29, NE)	NE (16.57, NE)	NE (12.43, NE)	NE (18.57, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	4.14, 26.43	1.86, 25.29	4.00, 26.29	2.86, 24.57	
Stratified Log-Rank Test p-value	0.066		0.32		
Adjusted Inverse Hazard Ratio (95% CI)	0.40 (0.15, 1.06)		0.55 (0.17, 1.84)		
Unstratified Log-Rank Test p-value	0.23		0.32		
Unadjusted Inverse Hazard Ratio (95% CI)	0.58 (0.23, 1.46)		0.55 (0.17, 1.85)		
P-value for interaction test					0.90

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment and baseline TD (yes,no).
Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.5001: Analysis of Time to RBC Transfusion Free Response
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Subjects with Event		
RBC Transfusion Free Response, n(%)	**27 (40.9%)**	**10 (25.6%)**
Censor		
Subjects Censored, n(%)	**39 (59.1%)**	**29 (74.4%)**
Kaplan-Meier Estimate of Time to RBC Transfusion Free Response (Weeks)		
25-percentile (95% CI)	**12.29 (12.14, 17.14)**	**18.57 (12.14, NE)**
Median (95% CI)	**NE (17.14, NE)**	**NE (NE, NE)**
75-percentile (95% CI)	**NE (NE, NE)**	**NE (NE, NE)**
Min, Max	**4.00, 26.43**	**1.86, 25.29**
Stratified Log-Rank Test p-value	**0.039**	
Adjusted Inverse Hazard Ratio (95% CI)	**0.45 (0.21, 0.96)**	
Unstratified Log-Rank Test p-value	**0.096**	
Unadjusted Inverse Hazard Ratio (95% CI)	**0.55 (0.27, 1.14)**	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion free response is defined as the absence of RBC transfusions in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

2.6.3 TD

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Table 2.4201: Analysis of Rate of New RBC Transfusion Dependent by Week 24
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are not Transfusion Dependent at Baseline

	MMB (N=14)	BAT (N=14)	Total (N=28)
New RBC Transfusion Dependent Rate by Week 24			
Not-Dependent, n(%)	3 (21.4%)	3 (21.4%)	6 (21.4%)
Dependent, n(%)	11 (78.6%)	11 (78.6%)	22 (78.6%)
95% Exact CI	0.4920, 0.9534	0.4920, 0.9534	0.5905, 0.9170
Proportion Difference - Stratified CMH Method(95% CI)	0.00(-0.34, 0.34)		
p-value	0.99		
Proportion Difference - Unstratified CMH Method (95% CI)	0.00(-0.33, 0.33)		
p-value	1.00		
Proportion Difference - Unstratified Exact Method(95% CI)	0.00(-0.39, 0.39)		
p-value	1.00		
Unadjusted Relative Risk (95% CI)	1.00 (0.68, 1.47)		
p-value [1]	1.00		
Unadjusted Odds Ratio (95% CI)	1.00 (0.16, 6.08)		
p-value [1]	1.00		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.30, 0.30)		
Adjusted Relative Risk (95% CI) [2]	1.00 (0.68, 1.47)		
p-value [2]	0.99		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tf-td-new-by24-gba.sas V.03.05 Output file: t-new-rbctd-rt-gba.pdf 24AUG2023:17:00

GSK Oncology

Study GS-US-352-1214

Table 2.4302: Analysis of RBC Transfusion Dependence Rate at Week 24 and at Week 12

Randomized Treatment Phase

ITT-Anemic Analysis Set Who are Not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
All Strata Combined			
RBC Transfusion Dependent Rate at Week 24			
Not-Dependent, n(%)	25 (41.0%)	7 (23.3%)	32 (35.2%)
Transfusion Requiring, n(%)	5 (8.2%)	6 (20.0%)	11 (12.1%)
Transfusion Independent, n(%)	20 (32.8%)	1 (3.3%)	21 (23.1%)
Dependent, n(%)	36 (59.0%)	23 (76.7%)	59 (64.8%)
95% Exact CI	0.4568, 0.7145	0.5772, 0.9007	0.5412, 0.7456
Proportion Difference - Stratified CMH Method (95% CI)	-0.15 (-0.36, 0.06)		
p-value	0.16		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.18 (-0.38, 0.02)		
p-value	0.083		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.18 (-0.39, 0.04)		
p-value	0.11		
Unadjusted Relative Risk (95% CI)	0.77 (0.58, 1.03)		
p-value [1]	0.075		
Unadjusted Odds Ratio (95% CI)	0.44 (0.16, 1.18)		
p-value [1]	0.10		
Unadjusted Absolute Risk Difference (95% CI)	-0.18 (-0.37, 0.02)		
Adjusted Relative Risk (95% CI) [2]	0.80 (0.61, 1.07)		
p-value [2]	0.13		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.

CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

Table 2.4302: Analysis of RBC Transfusion Dependence Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
>=4 units transfused in the last 8 weeks	14 (23.0%)	14 (46.7%)	28 (30.8%)
Any Hgb assessment < 8g/dL in the last 8 weeks	19 (31.1%)	13 (43.3%)	32 (35.2%)
Last Participation date < Day 162 in RT phase	15 (24.6%)	5 (16.7%)	20 (22.0%)
Other	7 (11.5%)	7 (23.3%)	14 (15.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

Table 2.4302: Analysis of RBC Transfusion Dependence Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
RBC Transfusion Dependent Rate at Week 12			
Not-Dependent, n(%)	20 (32.8%)	7 (23.3%)	27 (29.7%)
Transfusion Requiring, n(%)	8 (13.1%)	7 (23.3%)	15 (16.5%)
Transfusion Independent, n(%)	12 (19.7%)	0	12 (13.2%)
Dependent, n(%)	41 (67.2%)	23 (76.7%)	64 (70.3%)
95% Exact CI	0.5400, 0.7869	0.5772, 0.9007	0.5984, 0.7945
Proportion Difference - Stratified CMH Method (95% CI)	-0.07 (-0.28, 0.14)		
p-value	0.50		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.09 (-0.29, 0.10)		
p-value	0.34		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.09 (-0.31, 0.12)		
p-value	0.47		
Unadjusted Relative Risk (95% CI)	0.88 (0.67, 1.14)		
p-value [1]	0.33		
Unadjusted Odds Ratio (95% CI)	0.62 (0.23, 1.70)		
p-value [1]	0.36		
Unadjusted Absolute Risk Difference (95% CI)	-0.09 (-0.29, 0.10)		
Adjusted Relative Risk (95% CI) [2]	0.90 (0.70, 1.17)		
p-value [2]	0.45		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Table 2.4302: Analysis of RBC Transfusion Dependence Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
>=4 units transfused in the last 8 weeks	25 (41.0%)	13 (43.3%)	38 (41.8%)
Any Hgb assessment < 8g/dL in the last 8 weeks	32 (52.5%)	14 (46.7%)	46 (50.5%)
Last Participation date < Day 78 in RT phase	6 (9.8%)	4 (13.3%)	10 (11.0%)
Other	13 (21.3%)	9 (30.0%)	22 (24.2%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Table 2.4302: Analysis of RBC Transfusion Dependence Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
Stratum 1			
Transfusion Dependence Yes and Baseline TSS <18	35	14	49
RBC Transfusion Dependent Rate at Week 24			
Not-Dependent, n(%)	17 (48.6%)	5 (35.7%)	22 (44.9%)
Transfusion Requiring, n(%)	3 (8.6%)	5 (35.7%)	8 (16.3%)
Transfusion Independent, n(%)	14 (40.0%)	0	14 (28.6%)
Dependent, n(%)	18 (51.4%)	9 (64.3%)	27 (55.1%)
95% Exact CI	0.3399, 0.6862	0.3514, 0.8724	0.4023, 0.6933
Proportion Difference (95% CI)	-0.13 (-0.44, 0.18)		
Proportion Difference using Exact Method (95% CI)	-0.13 (-0.43, 0.19)		
>=4 units transfused in the last 8 weeks	6 (17.1%)	5 (35.7%)	11 (22.4%)
Any Hgb assessment < 8g/dL in the last 8 weeks	12 (34.3%)	6 (42.9%)	18 (36.7%)
Last Participation date < Day 162 in RT phase	6 (17.1%)	2 (14.3%)	8 (16.3%)
Other	6 (17.1%)	5 (35.7%)	11 (22.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Table 2.4302: Analysis of RBC Transfusion Dependence Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
RBC Transfusion Dependent Rate at Week 12			
Not-Dependent, n(%)	13 (37.1%)	4 (28.6%)	17 (34.7%)
Transfusion Requiring, n(%)	6 (17.1%)	4 (28.6%)	10 (20.4%)
Transfusion Independent, n(%)	7 (20.0%)	0	7 (14.3%)
Dependent, n(%)	22 (62.9%)	10 (71.4%)	32 (65.3%)
95% Exact CI	0.4492, 0.7853	0.4190, 0.9161	0.5036, 0.7833
Proportion Difference (95% CI)	-0.09(-0.38, 0.21)		
Proportion Difference using Exact Method (95% CI)	-0.09 (-0.39, 0.23)		
>=4 units transfused in the last 8 weeks	14 (40.0%)	6 (42.9%)	20 (40.8%)
Any Hgb assessment < 8g/dL in the last 8 weeks	21 (60.0%)	6 (42.9%)	27 (55.1%)
Last Participation date < Day 78 in RT phase	1 (2.9%)	2 (14.3%)	3 (6.1%)
Other	9 (25.7%)	5 (35.7%)	14 (28.6%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Table 2.4302: Analysis of RBC Transfusion Dependence Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
Stratum 2			
Transfusion Dependence Yes and Baseline TSS >=18	17	11	28
RBC Transfusion Dependent Rate at Week 24			
Not-Dependent, n(%)	5 (29.4%)	1 (9.1%)	6 (21.4%)
Transfusion Requiring, n(%)	2 (11.8%)	0	2 (7.1%)
Transfusion Independent, n(%)	3 (17.6%)	1 (9.1%)	4 (14.3%)
Dependent, n(%)	12 (70.6%)	10 (90.9%)	22 (78.6%)
95% Exact CI	0.4404, 0.8969	0.5872, 0.9977	0.5905, 0.9170
Proportion Difference (95% CI)	-0.20 (-0.51, 0.10)		
Proportion Difference using Exact Method (95% CI)	-0.20 (-0.54, 0.17)		
>=4 units transfused in the last 8 weeks	5 (29.4%)	7 (63.6%)	12 (42.9%)
Any Hgb assessment < 8g/dL in the last 8 weeks	5 (29.4%)	5 (45.5%)	10 (35.7%)
Last Participation date < Day 162 in RT phase	6 (35.3%)	2 (18.2%)	8 (28.6%)
Other	1 (5.9%)	2 (18.2%)	3 (10.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Table 2.4302: Analysis of RBC Transfusion Dependence Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
RBC Transfusion Dependent Rate at Week 12			
Not-Dependent, n(%)	3 (17.6%)	1 (9.1%)	4 (14.3%)
Transfusion Requiring, n(%)	0	1 (9.1%)	1 (3.6%)
Transfusion Independent, n(%)	3 (17.6%)	0	3 (10.7%)
Dependent, n(%)	14 (82.4%)	10 (90.9%)	24 (85.7%)
95% Exact CI	0.5657, 0.9620	0.5872, 0.9977	0.6733, 0.9597
Proportion Difference (95% CI)	-0.09(-0.37, 0.20)		
Proportion Difference using Exact Method (95% CI)	-0.09 (-0.44, 0.28)		
>=4 units transfused in the last 8 weeks	8 (47.1%)	5 (45.5%)	13 (46.4%)
Any Hgb assessment < 8g/dL in the last 8 weeks	9 (52.9%)	7 (63.6%)	16 (57.1%)
Last Participation date < Day 78 in RT phase	3 (17.6%)	2 (18.2%)	5 (17.9%)
Other	4 (23.5%)	3 (27.3%)	7 (25.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Table 2.4302: Analysis of RBC Transfusion Dependence Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
Stratum 3			
Transfusion Dependence No and Baseline TSS <18	5	2	7
RBC Transfusion Dependent Rate at Week 24			
Not-Dependent, n(%)	3 (60.0%)	0	3 (42.9%)
Transfusion Requiring, n(%)	0	0	0
Transfusion Independent, n(%)	3 (60.0%)	0	3 (42.9%)
Dependent, n(%)	2 (40.0%)	2 (100.0%)	4 (57.1%)
95% Exact CI	0.0527, 0.8534	0.1581, 1.0000	0.1841, 0.9010
Proportion Difference (95% CI)	-0.60 (-1.48, 0.28)		
Proportion Difference using Exact Method (95% CI)	-0.60 (-0.99, 0.32)		
>=4 units transfused in the last 8 weeks	0	0	0
Any Hgb assessment < 8g/dL in the last 8 weeks	0	1 (50.0%)	1 (14.3%)
Last Participation date < Day 162 in RT phase	2 (40.0%)	1 (50.0%)	3 (42.9%)
Other	0	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Table 2.4302: Analysis of RBC Transfusion Dependence Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
RBC Transfusion Dependent Rate at Week 12			
Not-Dependent, n(%)	3 (60.0%)	1 (50.0%)	4 (57.1%)
Transfusion Requiring, n(%)	1 (20.0%)	1 (50.0%)	2 (28.6%)
Transfusion Independent, n(%)	2 (40.0%)	0	2 (28.6%)
Dependent, n(%)	2 (40.0%)	1 (50.0%)	3 (42.9%)
95% Exact CI	0.0527, 0.8534	0.0126, 0.9874	0.0990, 0.8159
Proportion Difference (95% CI)	-0.10(-1.19, 0.99)		
Proportion Difference using Exact Method (95% CI)	-0.10 (-0.84, 0.67)		
>=4 units transfused in the last 8 weeks	1 (20.0%)	0	1 (14.3%)
Any Hgb assessment < 8g/dL in the last 8 weeks	1 (20.0%)	0	1 (14.3%)
Last Participation date < Day 78 in RT phase	1 (20.0%)	0	1 (14.3%)
Other	0	1 (50.0%)	1 (14.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

Table 2.4302: Analysis of RBC Transfusion Dependence Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
Stratum 4			
Transfusion Dependence No and Baseline TSS >=18	4	3	7
RBC Transfusion Dependent Rate at Week 24			
Not-Dependent, n(%)	0	1 (33.3%)	1 (14.3%)
Transfusion Requiring, n(%)	0	1 (33.3%)	1 (14.3%)
Transfusion Independent, n(%)	0	0	0
Dependent, n(%)	4 (100.0%)	2 (66.7%)	6 (85.7%)
95% Exact CI	0.3976, 1.0000	0.0943, 0.9916	0.4213, 0.9964
Proportion Difference (95% CI)	0.33 (-0.42, 1.09)		
Proportion Difference using Exact Method (95% CI)	0.33 (-0.43, 0.91)		
>=4 units transfused in the last 8 weeks	3 (75.0%)	2 (66.7%)	5 (71.4%)
Any Hgb assessment < 8g/dL in the last 8 weeks	2 (50.0%)	1 (33.3%)	3 (42.9%)
Last Participation date < Day 162 in RT phase	1 (25.0%)	0	1 (14.3%)
Other	0	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Table 2.4302: Analysis of RBC Transfusion Dependence Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
RBC Transfusion Dependent Rate at Week 12			
Not-Dependent, n(%)	1 (25.0%)	1 (33.3%)	2 (28.6%)
Transfusion Requiring, n(%)	1 (25.0%)	1 (33.3%)	2 (28.6%)
Transfusion Independent, n(%)	0	0	0
Dependent, n(%)	3 (75.0%)	2 (66.7%)	5 (71.4%)
95% Exact CI	0.1941, 0.9937	0.0943, 0.9916	0.2904, 0.9633
Proportion Difference (95% CI)	0.08(-0.76, 0.93)		
Proportion Difference using Exact Method (95% CI)	0.08 (-0.63, 0.76)		
>=4 units transfused in the last 8 weeks	2 (50.0%)	2 (66.7%)	4 (57.1%)
Any Hgb assessment < 8g/dL in the last 8 weeks	1 (25.0%)	1 (33.3%)	2 (28.6%)
Last Participation date < Day 78 in RT phase	1 (25.0%)	0	1 (14.3%)
Other	0	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Table 2.4303: Analysis of RBC Transfusion Dependence Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	MMB (N=52)	BAT (N=25)	Total (N=77)
All Strata Combined			
RBC Transfusion Dependent Rate at Week 24			
Not-Dependent, n(%)	22 (42.3%)	6 (24.0%)	28 (36.4%)
Transfusion Requiring, n(%)	5 (9.6%)	5 (20.0%)	10 (13.0%)
Transfusion Independent, n(%)	17 (32.7%)	1 (4.0%)	18 (23.4%)
Dependent, n(%)	30 (57.7%)	19 (76.0%)	49 (63.6%)
95% Exact CI	0.4320, 0.7127	0.5487, 0.9064	0.5188, 0.7430
Proportion Difference - Stratified CMH Method (95% CI)	-0.16 (-0.38, 0.06)		
p-value	0.16		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.18 (-0.40, 0.04)		
p-value	0.10		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.18 (-0.41, 0.05)		
p-value	0.14		
Unadjusted Relative Risk (95% CI)	0.76 (0.55, 1.05)		
p-value [1]	0.092		
Unadjusted Odds Ratio (95% CI)	0.43 (0.15, 1.26)		
p-value [1]	0.12		
Unadjusted Absolute Risk Difference (95% CI)	-0.18 (-0.40, 0.03)		
Adjusted Relative Risk (95% CI) [2]	0.79 (0.58, 1.08)		
p-value [2]	0.14		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline TSS (<18, >=18) as covariates.

Table 2.4303: Analysis of RBC Transfusion Dependence Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	MMB (N=52)	BAT (N=25)	Total (N=77)
>=4 units transfused in the last 8 weeks	11 (21.2%)	12 (48.0%)	23 (29.9%)
Any Hgb assessment < 8g/dL in the last 8 weeks	17 (32.7%)	11 (44.0%)	28 (36.4%)
Last Participation date < Day 162 in RT phase	12 (23.1%)	4 (16.0%)	16 (20.8%)
Other	7 (13.5%)	7 (28.0%)	14 (18.2%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

Table 2.4303: Analysis of RBC Transfusion Dependence Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	MMB (N=52)	BAT (N=25)	Total (N=77)
RBC Transfusion Dependent Rate at Week 12			
Not-Dependent, n(%)	16 (30.8%)	5 (20.0%)	21 (27.3%)
Transfusion Requiring, n(%)	6 (11.5%)	5 (20.0%)	11 (14.3%)
Transfusion Independent, n(%)	10 (19.2%)	0	10 (13.0%)
Dependent, n(%)	36 (69.2%)	20 (80.0%)	56 (72.7%)
95% Exact CI	0.5490, 0.8128	0.5930, 0.9317	0.6138, 0.8226
Proportion Difference - Stratified CMH Method (95% CI)	-0.09 (-0.30, 0.13)		
p-value	0.43		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.11 (-0.31, 0.10)		
p-value	0.31		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.11 (-0.34, 0.13)		
p-value	0.42		
Unadjusted Relative Risk (95% CI)	0.87 (0.66, 1.13)		
p-value [1]	0.29		
Unadjusted Odds Ratio (95% CI)	0.56 (0.18, 1.76)		
p-value [1]	0.32		
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.31, 0.09)		
Adjusted Relative Risk (95% CI) [2]	0.89 (0.69, 1.16)		
p-value [2]	0.39		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

Table 2.4303: Analysis of RBC Transfusion Dependence Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	MMB (N=52)	BAT (N=25)	Total (N=77)
>=4 units transfused in the last 8 weeks	22 (42.3%)	11 (44.0%)	33 (42.9%)
Any Hgb assessment < 8g/dL in the last 8 weeks	30 (57.7%)	13 (52.0%)	43 (55.8%)
Last Participation date < Day 78 in RT phase	4 (7.7%)	4 (16.0%)	8 (10.4%)
Other	13 (25.0%)	8 (32.0%)	21 (27.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

Table 2.4303: Analysis of RBC Transfusion Dependence Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	MMB (N=52)	BAT (N=25)	Total (N=77)
Stratum 1			
Transfusion Dependence Yes and Baseline TSS <18	35	14	49
RBC Transfusion Dependent Rate at Week 24			
Not-Dependent, n(%)	17 (48.6%)	5 (35.7%)	22 (44.9%)
Transfusion Requiring, n(%)	3 (8.6%)	5 (35.7%)	8 (16.3%)
Transfusion Independent, n(%)	14 (40.0%)	0	14 (28.6%)
Dependent, n(%)	18 (51.4%)	9 (64.3%)	27 (55.1%)
95% Exact CI	0.3399, 0.6862	0.3514, 0.8724	0.4023, 0.6933
Proportion Difference (95% CI)	-0.13 (-0.44, 0.18)		
Proportion Difference using Exact Method (95% CI)	-0.13 (-0.43, 0.19)		
>=4 units transfused in the last 8 weeks	6 (17.1%)	5 (35.7%)	11 (22.4%)
Any Hgb assessment < 8g/dL in the last 8 weeks	12 (34.3%)	6 (42.9%)	18 (36.7%)
Last Participation date < Day 162 in RT phase	6 (17.1%)	2 (14.3%)	8 (16.3%)
Other	6 (17.1%)	5 (35.7%)	11 (22.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

Table 2.4303: Analysis of RBC Transfusion Dependence Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	MMB (N=52)	BAT (N=25)	Total (N=77)
RBC Transfusion Dependent Rate at Week 12			
Not-Dependent, n(%)	13 (37.1%)	4 (28.6%)	17 (34.7%)
Transfusion Requiring, n(%)	6 (17.1%)	4 (28.6%)	10 (20.4%)
Transfusion Independent, n(%)	7 (20.0%)	0	7 (14.3%)
Dependent, n(%)	22 (62.9%)	10 (71.4%)	32 (65.3%)
95% Exact CI	0.4492, 0.7853	0.4190, 0.9161	0.5036, 0.7833
Proportion Difference (95% CI)	-0.09(-0.38, 0.21)		
Proportion Difference using Exact Method (95% CI)	-0.09 (-0.39, 0.23)		
>=4 units transfused in the last 8 weeks	14 (40.0%)	6 (42.9%)	20 (40.8%)
Any Hgb assessment < 8g/dL in the last 8 weeks	21 (60.0%)	6 (42.9%)	27 (55.1%)
Last Participation date < Day 78 in RT phase	1 (2.9%)	2 (14.3%)	3 (6.1%)
Other	9 (25.7%)	5 (35.7%)	14 (28.6%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

Table 2.4303: Analysis of RBC Transfusion Dependence Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	MMB (N=52)	BAT (N=25)	Total (N=77)
Stratum 2			
Transfusion Dependence Yes and Baseline TSS >=18	17	11	28
RBC Transfusion Dependent Rate at Week 24			
Not-Dependent, n(%)	5 (29.4%)	1 (9.1%)	6 (21.4%)
Transfusion Requiring, n(%)	2 (11.8%)	0	2 (7.1%)
Transfusion Independent, n(%)	3 (17.6%)	1 (9.1%)	4 (14.3%)
Dependent, n(%)	12 (70.6%)	10 (90.9%)	22 (78.6%)
95% Exact CI	0.4404, 0.8969	0.5872, 0.9977	0.5905, 0.9170
Proportion Difference (95% CI)	-0.20 (-0.51, 0.10)		
Proportion Difference using Exact Method (95% CI)	-0.20 (-0.54, 0.17)		
>=4 units transfused in the last 8 weeks	5 (29.4%)	7 (63.6%)	12 (42.9%)
Any Hgb assessment < 8g/dL in the last 8 weeks	5 (29.4%)	5 (45.5%)	10 (35.7%)
Last Participation date < Day 162 in RT phase	6 (35.3%)	2 (18.2%)	8 (28.6%)
Other	1 (5.9%)	2 (18.2%)	3 (10.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline TSS (<18, >=18) as covariates.

Table 2.4303: Analysis of RBC Transfusion Dependence Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	MMB (N=52)	BAT (N=25)	Total (N=77)
RBC Transfusion Dependent Rate at Week 12			
Not-Dependent, n(%)	3 (17.6%)	1 (9.1%)	4 (14.3%)
Transfusion Requiring, n(%)	0	1 (9.1%)	1 (3.6%)
Transfusion Independent, n(%)	3 (17.6%)	0	3 (10.7%)
Dependent, n(%)	14 (82.4%)	10 (90.9%)	24 (85.7%)
95% Exact CI	0.5657, 0.9620	0.5872, 0.9977	0.6733, 0.9597
Proportion Difference (95% CI)	-0.09(-0.37, 0.20)		
Proportion Difference using Exact Method (95% CI)	-0.09 (-0.44, 0.28)		
>=4 units transfused in the last 8 weeks	8 (47.1%)	5 (45.5%)	13 (46.4%)
Any Hgb assessment < 8g/dL in the last 8 weeks	9 (52.9%)	7 (63.6%)	16 (57.1%)
Last Participation date < Day 78 in RT phase	3 (17.6%)	2 (18.2%)	5 (17.9%)
Other	4 (23.5%)	3 (27.3%)	7 (25.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline TSS (<18, >=18) as covariates.

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Table 2.4301: Analysis of RBC Transfusion Dependence Rate at Week 24 and at Week 12

Randomized Treatment Phase

ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=5)	BAT (N=9)	Total (N=14)
All Strata Combined			
RBC Transfusion Dependent Rate at Week 24			
Not-Dependent, n(%)	2 (40.0%)	4 (44.4%)	6 (42.9%)
Transfusion Requiring, n(%)	0	0	0
Transfusion Independent, n(%)	2 (40.0%)	4 (44.4%)	6 (42.9%)
Dependent, n(%)	3 (60.0%)	5 (55.6%)	8 (57.1%)
95% Exact CI	0.1466, 0.9473	0.2120, 0.8630	0.2886, 0.8234
Proportion Difference - Stratified CMH Method (95% CI)	0.04 (-0.64, 0.71)		
p-value	0.91		
Proportion Difference - Unstratified CMH Method (95% CI)	0.04 (-0.55, 0.64)		
p-value	0.88		
Proportion Difference - Unstratified Exact Method (95% CI)	0.04 (-0.50, 0.55)		
p-value	1.00		
Unadjusted Relative Risk (95% CI)	1.08 (0.43, 2.72)		
p-value [1]	0.87		
Unadjusted Odds Ratio (95% CI)	1.20 (0.13, 11.05)		
p-value [1]	0.87		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.49, 0.58)		
Adjusted Relative Risk (95% CI) [2]	1.07 (0.43, 2.67)		
p-value [2]	0.89		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.

CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

Table 2.4301: Analysis of RBC Transfusion Dependence Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=5)	BAT (N=9)	Total (N=14)
>=4 units transfused in the last 8 weeks	0	1 (11.1%)	1 (7.1%)
Any Hgb assessment < 8g/dL in the last 8 weeks	0	2 (22.2%)	2 (14.3%)
Last Participation date < Day 162 in RT phase	3 (60.0%)	2 (22.2%)	5 (35.7%)
Other	0	1 (11.1%)	1 (7.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

Table 2.4301: Analysis of RBC Transfusion Dependence Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=5)	BAT (N=9)	Total (N=14)
RBC Transfusion Dependent Rate at Week 12			
Not-Dependent, n(%)	3 (60.0%)	5 (55.6%)	8 (57.1%)
Transfusion Requiring, n(%)	0	2 (22.2%)	2 (14.3%)
Transfusion Independent, n(%)	3 (60.0%)	3 (33.3%)	6 (42.9%)
Dependent, n(%)	2 (40.0%)	4 (44.4%)	6 (42.9%)
95% Exact CI	0.0527, 0.8534	0.1370, 0.7880	0.1766, 0.7114
Proportion Difference - Stratified CMH Method (95% CI)	-0.04 (-0.71, 0.64)		
p-value	0.91		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.04 (-0.64, 0.55)		
p-value	0.88		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.04 (-0.55, 0.50)		
p-value	1.00		
Unadjusted Relative Risk (95% CI)	0.90 (0.25, 3.30)		
p-value [1]	0.87		
Unadjusted Odds Ratio (95% CI)	0.83 (0.09, 7.68)		
p-value [1]	0.87		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.58, 0.49)		
Adjusted Relative Risk (95% CI) [2]	0.91 (0.25, 3.30)		
p-value [2]	0.89		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

Table 2.4301: Analysis of RBC Transfusion Dependence Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=5)	BAT (N=9)	Total (N=14)
>=4 units transfused in the last 8 weeks	1 (20.0%)	0	1 (7.1%)
Any Hgb assessment < 8g/dL in the last 8 weeks	1 (20.0%)	2 (22.2%)	3 (21.4%)
Last Participation date < Day 78 in RT phase	1 (20.0%)	2 (22.2%)	3 (21.4%)
Other	0	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

Table 2.4301: Analysis of RBC Transfusion Dependence Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=5)	BAT (N=9)	Total (N=14)
Stratum 3			
Transfusion Dependence No and Baseline TSS <18	2	4	6
RBC Transfusion Dependent Rate at Week 24			
Not-Dependent, n(%)	1 (50.0%)	2 (50.0%)	3 (50.0%)
Transfusion Requiring, n(%)	0	0	0
Transfusion Independent, n(%)	1 (50.0%)	2 (50.0%)	3 (50.0%)
Dependent, n(%)	1 (50.0%)	2 (50.0%)	3 (50.0%)
95% Exact CI	0.0126, 0.9874	0.0676, 0.9324	0.1181, 0.8819
Proportion Difference (95% CI)	0.00 (-1.13, 1.13)		
Proportion Difference using Exact Method (95% CI)	0.00 (-0.84, 0.84)		
>=4 units transfused in the last 8 weeks	0	1 (25.0%)	1 (16.7%)
Any Hgb assessment < 8g/dL in the last 8 weeks	0	1 (25.0%)	1 (16.7%)
Last Participation date < Day 162 in RT phase	1 (50.0%)	0	1 (16.7%)
Other	0	1 (25.0%)	1 (16.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

Table 2.4301: Analysis of RBC Transfusion Dependence Rate at Week 24 and at Week 12
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=5)	BAT (N=9)	Total (N=14)
RBC Transfusion Dependent Rate at Week 12			
Not-Dependent, n(%)	1 (50.0%)	2 (50.0%)	3 (50.0%)
Transfusion Requiring, n(%)	0	1 (25.0%)	1 (16.7%)
Transfusion Independent, n(%)	1 (50.0%)	1 (25.0%)	2 (33.3%)
Dependent, n(%)	1 (50.0%)	2 (50.0%)	3 (50.0%)
95% Exact CI	0.0126, 0.9874	0.0676, 0.9324	0.1181, 0.8819
Proportion Difference (95% CI)	0.00(-1.13, 1.13)		
Proportion Difference using Exact Method (95% CI)	0.00 (-0.84, 0.84)		
>=4 units transfused in the last 8 weeks	0	0	0
Any Hgb assessment < 8g/dL in the last 8 weeks	0	2 (50.0%)	2 (33.3%)
Last Participation date < Day 78 in RT phase	1 (50.0%)	0	1 (16.7%)
Other	0	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline TSS (<18, >=18) as covariates.

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Table 2.4301: Analysis of RBC Transfusion Dependence Rate at Week 24 and at Week 12

Randomized Treatment Phase

ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=5)	BAT (N=9)	Total (N=14)
Stratum 4			
Transfusion Dependence No and Baseline TSS >=18	3	5	8
RBC Transfusion Dependent Rate at Week 24			
Not-Dependent, n(%)	1 (33.3%)	2 (40.0%)	3 (37.5%)
Transfusion Requiring, n(%)	0	0	0
Transfusion Independent, n(%)	1 (33.3%)	2 (40.0%)	3 (37.5%)
Dependent, n(%)	2 (66.7%)	3 (60.0%)	5 (62.5%)
95% Exact CI	0.0943, 0.9916	0.1466, 0.9473	0.2449, 0.9148
Proportion Difference (95% CI)	0.07 (-0.76, 0.89)		
Proportion Difference using Exact Method (95% CI)	0.07 (-0.63, 0.71)		
>=4 units transfused in the last 8 weeks	0	0	0
Any Hgb assessment < 8g/dL in the last 8 weeks	0	1 (20.0%)	1 (12.5%)
Last Participation date < Day 162 in RT phase	2 (66.7%)	2 (40.0%)	4 (50.0%)
Other	0	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.

CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline TSS (<18, >=18) as covariates.

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Table 2.4301: Analysis of RBC Transfusion Dependence Rate at Week 24 and at Week 12

Randomized Treatment Phase

ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=5)	BAT (N=9)	Total (N=14)
RBC Transfusion Dependent Rate at Week 12			
Not-Dependent, n(%)	2 (66.7%)	3 (60.0%)	5 (62.5%)
Transfusion Requiring, n(%)	0	1 (20.0%)	1 (12.5%)
Transfusion Independent, n(%)	2 (66.7%)	2 (40.0%)	4 (50.0%)
Dependent, n(%)	1 (33.3%)	2 (40.0%)	3 (37.5%)
95% Exact CI	0.0084, 0.9057	0.0527, 0.8534	0.0852, 0.7551
Proportion Difference (95% CI)	-0.07(-0.89, 0.76)		
Proportion Difference using Exact Method (95% CI)	-0.07 (-0.71, 0.63)		
>=4 units transfused in the last 8 weeks	1 (33.3%)	0	1 (12.5%)
Any Hgb assessment < 8g/dL in the last 8 weeks	1 (33.3%)	0	1 (12.5%)
Last Participation date < Day 78 in RT phase	0	2 (40.0%)	2 (25.0%)
Other	0	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.

CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment and baseline TSS (<18, >=18) as covariates.

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Table 2.4102: Analysis of Rate of RBC Transfusion Dependence by Week 24 by Age

Randomized Treatment Phase

ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
RBC Transfusion Dependent Rate by Week 24					
Not-Dependent, n(%)	3 (12.5%)	1 (11.1%)	10 (23.8%)	3 (10.0%)	
Dependent, n(%)	21 (87.5%)	8 (88.9%)	32 (76.2%)	27 (90.0%)	
95% Exact CI	0.6764, 0.9734	0.5175, 0.9972	0.6055, 0.8795	0.7347, 0.9789	
Proportion Difference - Stratified CMH Method (95% CI)	0.01 (-0.33, 0.35)		-0.16 (-0.35, 0.04)		
p-value	0.94		0.11		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.01 (-0.30, 0.27)		-0.14 (-0.31, 0.04)		
p-value	0.92		0.12		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.01 (-0.39, 0.37)		-0.14 (-0.36, 0.10)		
p-value	1.00		0.21		
Unadjusted Relative Risk (95% CI)	0.98 (0.75, 1.30)		0.85 (0.69, 1.04)		
p-value [1]	0.91		0.11		
Unadjusted interaction test for Treatment*Age Group [3]					0.39
Unadjusted Odds Ratio (95% CI)	0.88 (0.08, 9.70)		0.36 (0.09, 1.42)		
p-value [1]	0.91		0.14		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.26, 0.23)		-0.14 (-0.31, 0.03)		
Adjusted Relative Risk (95% CI) [2]	1.02 (0.79, 1.30)		0.83 (0.68, 1.01)		
p-value [2]	0.90		0.066		
Adjusted interaction test for Treatment*Age Group [3]					0.29

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel; RBC = Red Blood Cell

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.4108: Analysis of Rate of RBC Transfusion Dependence by Week 24 by Baseline MF Disease Status

Randomized Treatment Phase

ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
RBC Transfusion Dependent Rate by Week 24				
Not-Dependent, n(%)	8 (17.8%)	2 (8.7%)	2 (15.4%)	1 (12.5%)
Dependent, n(%)	37 (82.2%)	21 (91.3%)	11 (84.6%)	7 (87.5%)
95% Exact CI	0.6795, 0.9200	0.7196, 0.9893	0.5455, 0.9808	0.4735, 0.9968
Proportion Difference - Stratified CMH Method (95% CI)	-0.09 (-0.30, 0.11)		-0.01 (-0.38, 0.37)	
p-value	0.36		0.98	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.09 (-0.26, 0.08)		-0.03 (-0.38, 0.32)	
p-value	0.30		0.87	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.09 (-0.33, 0.16)		-0.03 (-0.44, 0.40)	
p-value	0.48		1.00	
Unadjusted Relative Risk (95% CI)	0.90 (0.75, 1.08)		0.97 (0.68, 1.37)	
p-value [1]	0.27		0.85	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	0.44 (0.09, 2.27)		0.79 (0.06, 10.38)	
p-value [1]	0.33		0.85	
Unadjusted Absolute Risk Difference (95% CI)	-0.09 (-0.25, 0.07)		-0.03 (-0.33, 0.27)	
Adjusted Relative Risk (95% CI) [2]	0.90 (0.75, 1.08)		NE	
p-value [2]	0.25		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel; RBC = Red Blood Cell

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.4108: Analysis of Rate of RBC Transfusion Dependence by Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
RBC Transfusion Dependent Rate by Week 24			
Not-Dependent, n(%)	3 (37.5%)	1 (12.5%)	
Dependent, n(%)	5 (62.5%)	7 (87.5%)	
95% Exact CI	0.2449, 0.9148	0.4735, 0.9968	
Proportion Difference - Stratified CMH Method (95% CI)	-0.35 (-0.92, 0.21)		
p-value	0.22		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.25 (-0.70, 0.20)		
p-value	0.28		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.25 (-0.70, 0.29)		
p-value	0.57		
Unadjusted Relative Risk (95% CI)	0.71 (0.39, 1.30)		
p-value [1]	0.27		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.67
Unadjusted Odds Ratio (95% CI)	0.24 (0.02, 3.01)		
p-value [1]	0.27		
Unadjusted Absolute Risk Difference (95% CI)	-0.25 (-0.66, 0.16)		
Adjusted Relative Risk (95% CI) [2]	0.64 (0.39, 1.07)		
p-value [2]	0.087		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.56

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel; RBC = Red Blood Cell
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

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Table 2.4107: Analysis of Rate of RBC Transfusion Dependence by Week 24 by Baseline Hemoglobin Level

Randomized Treatment Phase

ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
RBC Transfusion Dependent Rate by Week 24					
Not-Dependent, n(%)	2 (7.4%)	0	11 (28.2%)	4 (12.1%)	
Dependent, n(%)	25 (92.6%)	6 (100.0%)	28 (71.8%)	29 (87.9%)	
95% Exact CI	0.7571, 0.9909	0.5407, 1.0000	0.5513, 0.8500	0.7180, 0.9660	
Proportion Difference - Stratified CMH Method (95% CI)	-0.08 (-0.42, 0.27)		-0.16 (-0.36, 0.05)		
p-value	0.67		0.13		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.07 (-0.33, 0.18)		-0.16 (-0.35, 0.02)		
p-value	0.56		0.090		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.07 (-0.51, 0.37)		-0.16 (-0.38, 0.07)		
p-value	1.00		0.15		
Unadjusted Relative Risk (95% CI)	0.98 (0.77, 1.24)		0.82 (0.65, 1.03)		
p-value [1]	0.87		0.090		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.36
Unadjusted Odds Ratio (95% CI)	0.78 (0.03, 18.42)		0.35 (0.10, 1.23)		
p-value [1]	0.88		0.10		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.24, 0.20)		-0.16 (-0.34, 0.02)		
Adjusted Relative Risk (95% CI) [2]	0.92 (0.83, 1.03)		0.82 (0.65, 1.04)		
p-value [2]	0.16		0.10		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.35

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel; RBC = Red Blood Cell

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.4106: Analysis of Rate of RBC Transfusion Dependence by Week 24 by Baseline DIPSS Two-Level Risk

Randomized Treatment Phase

ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
RBC Transfusion Dependent Rate by Week 24					
Not-Dependent, n(%)	10 (20.4%)	4 (12.9%)	3 (17.6%)	0	
Dependent, n(%)	39 (79.6%)	27 (87.1%)	14 (82.4%)	8 (100.0%)	
95% Exact CI	0.6566, 0.8976	0.7017, 0.9637	0.5657, 0.9620	0.6306, 1.0000	
Proportion Difference - Stratified CMH Method (95% CI)	-0.11 (-0.30, 0.08)		-0.22 (-0.57, 0.13)		
p-value	0.26		0.21		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.08 (-0.24, 0.09)		-0.18 (-0.43, 0.08)		
p-value	0.39		0.18		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.08 (-0.29, 0.15)		-0.18 (-0.55, 0.23)		
p-value	0.55		0.53		
Unadjusted Relative Risk (95% CI)	0.91 (0.75, 1.11)		0.85 (0.65, 1.12)		
p-value [1]	0.37		0.26		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					0.48
Unadjusted Odds Ratio (95% CI)	0.58 (0.16, 2.04)		0.24 (0.01, 5.31)		
p-value [1]	0.39		0.37		
Unadjusted Absolute Risk Difference (95% CI)	-0.08 (-0.24, 0.09)		-0.14 (-0.38, 0.10)		
Adjusted Relative Risk (95% CI) [2]	0.88 (0.72, 1.07)		0.78 (0.58, 1.04)		
p-value [2]	0.19		0.087		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					0.70

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel; RBC = Red Blood Cell

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.4105: Analysis of Rate of RBC Transfusion Dependence by Week 24 by Baseline DIPSS Three-Level Risk

Randomized Treatment Phase

ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
RBC Transfusion Dependent Rate by Week 24				
Not-Dependent, n(%)	2 (40.0%)	1 (14.3%)	8 (18.2%)	3 (12.5%)
Dependent, n(%)	3 (60.0%)	6 (85.7%)	36 (81.8%)	21 (87.5%)
95% Exact CI	0.1466, 0.9473	0.4213, 0.9964	0.6729, 0.9181	0.6764, 0.9734
Proportion Difference - Stratified CMH Method (95% CI)	0.33 (-0.48, 1.15)		-0.10 (-0.31, 0.11)	
p-value	0.42		0.37	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.26 (-0.83, 0.32)		-0.06 (-0.24, 0.13)	
p-value	0.38		0.54	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.26 (-0.74, 0.32)		-0.06 (-0.30, 0.19)	
p-value	0.52		0.73	
Unadjusted Relative Risk (95% CI)	0.70 (0.32, 1.52)		0.94 (0.76, 1.15)	
p-value [1]	0.37		0.52	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	0.25 (0.02, 4.00)		0.64 (0.15, 2.69)	
p-value [1]	0.33		0.55	
Unadjusted Absolute Risk Difference (95% CI)	-0.26 (-0.76, 0.24)		-0.06 (-0.23, 0.12)	
Adjusted Relative Risk (95% CI) [2]	NE		0.89 (0.75, 1.07)	
p-value [2]	NE		0.21	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel; RBC = Red Blood Cell

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.4105: Analysis of Rate of RBC Transfusion Dependence by Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
RBC Transfusion Dependent Rate by Week 24			
Not-Dependent, n(%)	3 (17.6%)	0	
Dependent, n(%)	14 (82.4%)	8 (100.0%)	
95% Exact CI	0.5657, 0.9620	0.6306, 1.0000	
Proportion Difference - Stratified CMH Method (95% CI)	-0.22 (-0.57, 0.13)		
p-value	0.21		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.18 (-0.43, 0.08)		
p-value	0.18		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.18 (-0.55, 0.23)		
p-value	0.53		
Unadjusted Relative Risk (95% CI)	0.85 (0.65, 1.12)		
p-value [1]	0.26		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			0.59
Unadjusted Odds Ratio (95% CI)	0.24 (0.01, 5.31)		
p-value [1]	0.37		
Unadjusted Absolute Risk Difference (95% CI)	-0.14 (-0.38, 0.10)		
Adjusted Relative Risk (95% CI) [2]	0.78 (0.58, 1.04)		
p-value [2]	0.087		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			0.82

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel; RBC = Red Blood Cell
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

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Table 2.4104: Analysis of Rate of RBC Transfusion Dependence by Week 24 by Region

Randomized Treatment Phase

ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
RBC Transfusion Dependent Rate by Week 24					
Not-Dependent, n(%)	8 (27.6%)	2 (28.6%)	5 (13.5%)	2 (6.3%)	
Dependent, n(%)	21 (72.4%)	5 (71.4%)	32 (86.5%)	30 (93.8%)	
95% Exact CI	0.5276, 0.8727	0.2904, 0.9633	0.7123, 0.9546	0.7919, 0.9923	
Proportion Difference - Stratified CMH Method (95% CI)	-0.05 (-0.45, 0.36)		-0.06 (-0.24, 0.11)		
p-value	0.83		0.47		
Proportion Difference - Unstratified CMH Method (95% CI)	0.01 (-0.40, 0.42)		-0.07 (-0.22, 0.08)		
p-value	0.96		0.34		
Proportion Difference - Unstratified Exact Method (95% CI)	0.01 (-0.40, 0.42)		-0.07 (-0.30, 0.16)		
p-value	1.00		0.44		
Unadjusted Relative Risk (95% CI)	1.01 (0.60, 1.70)		0.92 (0.79, 1.08)		
p-value [1]	0.96		0.31		
Unadjusted interaction test for Treatment*Region [3]					0.73
Unadjusted Odds Ratio (95% CI)	1.05 (0.17, 6.55)		0.43 (0.08, 2.37)		
p-value [1]	0.96		0.33		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.36, 0.38)		-0.07 (-0.21, 0.07)		
Adjusted Relative Risk (95% CI) [2]	0.94 (0.65, 1.35)		0.93 (0.80, 1.08)		
p-value [2]	0.73		0.35		
Adjusted interaction test for Treatment*Region [3]					0.68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel; RBC = Red Blood Cell

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.4103: Analysis of Rate of RBC Transfusion Dependence by Week 24 by Gender

Randomized Treatment Phase

ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
RBC Transfusion Dependent Rate by Week 24					
Not-Dependent, n(%)	9 (17.3%)	0	4 (28.6%)	4 (19.0%)	
Dependent, n(%)	43 (82.7%)	18 (100.0%)	10 (71.4%)	17 (81.0%)	
95% Exact CI	0.6967, 0.9177	0.8147, 1.0000	0.4190, 0.9161	0.5809, 0.9455	
Proportion Difference - Stratified CMH Method (95% CI)	-0.17 (-0.36, 0.02)		-0.12 (-0.44, 0.21)		
p-value	0.079		0.48		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.17 (-0.30, -0.04		-0.10 (-0.40, 0.21)		
p-value	0.009		0.54		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.17 (-0.43, 0.09)		-0.10 (-0.43, 0.25)		
p-value	0.099		0.69		
Unadjusted Relative Risk (95% CI)	0.84 (0.73, 0.98)		0.88 (0.60, 1.30)		
p-value [1]	0.022		0.53		
Unadjusted interaction test for Treatment*Gender [3]					0.76
Unadjusted Odds Ratio (95% CI)	0.12 (0.01, 2.24)		0.59 (0.12, 2.89)		
p-value [1]	0.16		0.51		
Unadjusted Absolute Risk Difference (95% CI)	-0.15 (-0.28, -0.03		-0.10 (-0.39, 0.19)		
Adjusted Relative Risk (95% CI) [2]	0.83 (0.73, 0.94)		0.86 (0.59, 1.26)		
p-value [2]	0.003		0.45		
Adjusted interaction test for Treatment*Gender [3]					0.86

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel; RBC = Red Blood Cell

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

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Table 2.4110: Analysis of Rate of RBC Transfusion Dependence by Week 24 by Baseline Spleen Volume

Randomized Treatment Phase

ITT-Anemic Analysis Set

	<Median (2329.91 cm^3)		>=Median (2329.91 cm^3)		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
RBC Transfusion Dependent Rate by Week 24					
Not-Dependent, n(%)	6 (21.4%)	3 (12.5%)	7 (18.4%)	1 (6.7%)	
Dependent, n(%)	22 (78.6%)	21 (87.5%)	31 (81.6%)	14 (93.3%)	
95% Exact CI	0.5905, 0.9170	0.6764, 0.9734	0.6567, 0.9226	0.6805, 0.9983	
Proportion Difference - Stratified CMH Method (95% CI)	-0.10 (-0.35, 0.15)		-0.13 (-0.40, 0.15)		
p-value	0.43		0.37		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.09 (-0.30, 0.12)		-0.12 (-0.32, 0.08)		
p-value	0.41		0.25		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.09 (-0.35, 0.18)		-0.12 (-0.40, 0.18)		
p-value	0.48		0.42		
Unadjusted Relative Risk (95% CI)	0.90 (0.70, 1.15)		0.87 (0.71, 1.07)		
p-value [1]	0.39		0.19		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.87
Unadjusted Odds Ratio (95% CI)	0.52 (0.12, 2.37)		0.32 (0.04, 2.82)		
p-value [1]	0.40		0.30		
Unadjusted Absolute Risk Difference (95% CI)	-0.09 (-0.29, 0.11)		-0.12 (-0.29, 0.06)		
Adjusted Relative Risk (95% CI) [2]	0.89 (0.69, 1.14)		0.87 (0.73, 1.02)		
p-value [2]	0.34		0.087		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.77

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel; RBC = Red Blood Cell

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

GSK Oncology

Study GS-US-352-1214

Table 2.4109: Analysis of Rate of RBC Transfusion Dependence by Week 24 by Baseline TSS

Randomized Treatment Phase

ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
RBC Transfusion Dependent Rate by Week 24					
Not-Dependent, n(%)	9 (21.4%)	2 (10.0%)	4 (16.7%)	2 (10.5%)	
Dependent, n(%)	33 (78.6%)	18 (90.0%)	20 (83.3%)	17 (89.5%)	
95% Exact CI	0.6319, 0.8970	0.6830, 0.9877	0.6262, 0.9526	0.6686, 0.9870	
Proportion Difference - Stratified CMH Method (95% CI)	-0.13 (-0.33, 0.08)		-0.07 (-0.29, 0.15)		
p-value	0.23		0.51		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.11 (-0.31, 0.08)		-0.06 (-0.28, 0.16)		
p-value	0.25		0.58		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.11 (-0.37, 0.15)		-0.06 (-0.35, 0.24)		
p-value	0.48		0.68		
Unadjusted Relative Risk (95% CI)	0.87 (0.70, 1.08)		0.93 (0.74, 1.18)		
p-value [1]	0.22		0.56		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.69
Unadjusted Odds Ratio (95% CI)	0.41 (0.08, 2.09)		0.59 (0.10, 3.62)		
p-value [1]	0.28		0.57		
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.30, 0.07)		-0.06 (-0.26, 0.14)		
Adjusted Relative Risk (95% CI) [2]	0.86 (0.69, 1.07)		0.92 (0.74, 1.14)		
p-value [2]	0.17		0.44		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.69

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

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

CMH = Cochran-Mantel-Haenszel; RBC = Red Blood Cell

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.

[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

GSK Oncology
Study GS-US-352-1214

Table 2.4101: Analysis of Rate of RBC Transfusion Dependence by Week 24
Randomized Treatment Phase
ITT-Anemic Analysis Set

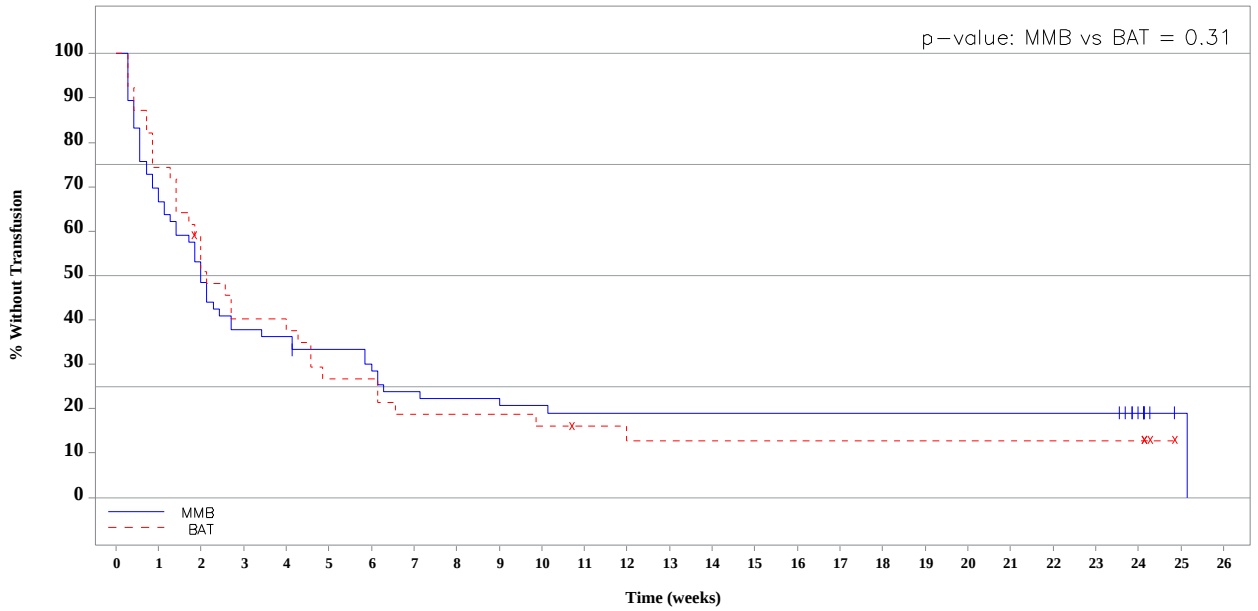
	MMB (N=66)	BAT (N=39)	Total (N=105)
RBC Transfusion Dependent Rate by Week 24			
Not-Dependent, n(%)	13 (19.7%)	4 (10.3%)	17 (16.2%)
Dependent, n(%)	53 (80.3%)	35 (89.7%)	88 (83.8%)
95% Exact CI	0.6868, 0.8907	0.7578, 0.9713	0.7535, 0.9028
Proportion Difference - Stratified CMH Method (95% CI)	-0.10 (-0.25, 0.05)		
p-value	0.18		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.09 (-0.23, 0.05)		
p-value	0.19		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.09 (-0.29, 0.11)		
p-value	0.28		
Unadjusted Relative Risk (95% CI)	0.89 (0.76, 1.05)		
p-value [1]	0.17		
Unadjusted Odds Ratio (95% CI)	0.47 (0.14, 1.55)		
p-value [1]	0.21		
Unadjusted Absolute Risk Difference (95% CI)	-0.09 (-0.23, 0.04)		
Adjusted Relative Risk (95% CI) [2]	0.89 (0.76, 1.03)		
p-value [2]	0.12		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

2.6.4 Sonstige

Figure 2.2701: Kaplan-Meier Plot of Time to First Unit of Any Type Transfused
Randomized Treatment Phase
ITT-Anemic Analysis Set



N at Risk (Events)

MMB	66 (0)	46 (22)	35 (34)	25 (41)	24 (42)	21 (44)	19 (47)	15 (50)	14 (51)	14 (52)	13 (52)	12 (53)	12 (53)	12 (53)	12 (53)	12 (53)	12 (53)	12 (53)	12 (53)	12 (53)	12 (53)	12 (53)	12 (53)	12 (53)	8 (53)	1 (53)	0 (54)
BAT	39 (0)	29 (10)	22 (19)	15 (23)	15 (24)	10 (28)	10 (28)	7 (31)	7 (31)	7 (31)	6 (32)	5 (32)	5 (33)	4 (33)	4 (33)	4 (33)	4 (33)	4 (33)	4 (33)	4 (33)	4 (33)	4 (33)	4 (33)	4 (33)	4 (33)	0 (33)	0 (33)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-tte-any-tran.sas V.03.05 Output file: g-tte-any-tran.pdf 25AUG2023:12:36

Table 2.2602: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)	
All Strata Combined				
RBC transfusion Rate in RT phase (units/month)				
N	61	30	91	
Mean (SD)	2.2 (2.15)	2.4 (2.02)	2.3 (2.10)	
Median	1.7	1.8	1.8	
Q1, Q3	0.4, 3.3	1.0, 3.1	0.7, 3.3	
Min, Max	0.0, 8.2	0.0, 7.6	0.0, 8.2	
Negative Binomial Model				
Adjusted for Strata				
Rate of RBC transfusion with 95% CI (units/month)	1.78 (1.28, 2.50)	1.77 (1.16, 2.72)		
Ratio of Rate for RBC Transfusion with 95% CI	1.01 (0.64, 1.57)	-	-	
p-value	0.98	-	-	
Unadjusted for Strata				
Rate of RBC transfusion with 95% CI (units/month)	2.18 (1.68, 2.83)	2.35 (1.61, 3.42)		
Ratio of Rate for RBC Transfusion with 95% CI	0.93 (0.59, 1.46)	-	-	
p-value	0.74	-	-	
Proportional Means Model - Supportive Analysis				
Stratified				
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.97 (0.69, 1.36)	-	-	
p-value	0.85	-	-	
Unstratified				
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.94 (0.65, 1.36)	-	-	
p-value	0.74	-	-	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

Table 2.2602: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
Total number of RBC transfusion unit in RT phase			
N	61	30	91
Mean (SD)	10.2 (10.37)	10.7 (8.42)	10.4 (9.73)
Median	7.0	8.0	8.0
Q1, Q3	2.0, 15.0	5.0, 14.0	3.0, 15.0
Min, Max	0.0, 38.0	0.0, 40.0	0.0, 40.0
Duration of the RT phase (months)			
N	61	30	91
Mean (SD)	4.96 (1.360)	4.91 (1.584)	4.94 (1.429)
Median	5.55	5.55	5.55
Q1, Q3	5.42, 5.68	5.42, 5.65	5.42, 5.65
Min, Max	0.92, 5.78	0.43, 5.78	0.43, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

Table 2.2602: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
Stratum 1			
Transfusion Dependence at Baseline = 'Yes' and TSS < 18 at Baseline			
RBC transfusion Rate in RT phase (units/month)			
N	35	14	49
Mean (SD)	2.1 (2.14)	2.0 (1.50)	2.0 (1.96)
Median	1.0	1.3	1.3
Q1, Q3	0.4, 3.3	0.9, 3.0	0.5, 3.1
Min, Max	0.0, 6.8	0.0, 5.0	0.0, 6.8
Negative Binomial Model			
Rate of RBC transfusion with 95% CI (units/month)	2.05 (1.44, 2.91)	2.03 (1.15, 3.57)	
Ratio of Rate for RBC Transfusion with 95% CI	1.01 (0.52, 1.97)	-	-
Proportional Means Model - Supportive Analysis			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	1.02 (0.63, 1.66)	-	-
Total number of RBC transfusion in stratum 1 in RT phase			
N	35	14	49
Mean (SD)	10.6 (11.47)	9.8 (7.06)	10.4 (10.33)
Median	6.0	7.5	7.0
Q1, Q3	2.0, 16.0	5.0, 16.0	2.0, 16.0
Min, Max	0.0, 38.0	0.0, 25.0	0.0, 38.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

Table 2.2602: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
Duration of the RT phase (months) in stratum 1			
N	35	14	49
Mean (SD)	5.27 (0.854)	4.96 (1.690)	5.18 (1.145)
Median	5.55	5.55	5.55
Q1, Q3	5.49, 5.72	5.49, 5.75	5.49, 5.72
Min, Max	2.14, 5.78	0.43, 5.78	0.43, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Table 2.2602: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
Stratum 2			
Transfusion Dependence at Baseline = 'Yes' and TSS >= 18 at Baseline			
RBC transfusion Rate in RT phase (units/month)			
N	17	11	28
Mean (SD)	2.9 (2.47)	3.5 (2.45)	3.1 (2.44)
Median	2.2	2.5	2.4
Q1, Q3	0.7, 4.5	1.4, 6.2	1.3, 5.2
Min, Max	0.0, 8.2	1.0, 7.6	0.0, 8.2
Negative Binomial Model			
Rate of RBC transfusion with 95% CI (units/month)	2.79 (1.80, 4.32)	3.37 (1.96, 5.80)	
Ratio of Rate for RBC Transfusion with 95% CI	0.83 (0.41, 1.66)	-	-
Proportional Means Model - Supportive Analysis			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.81 (0.45, 1.45)	-	-
Total number of RBC transfusion in stratum 2 in RT phase			
N	17	11	28
Mean (SD)	11.2 (9.78)	14.0 (10.25)	12.3 (9.88)
Median	9.0	10.0	10.0
Q1, Q3	4.0, 16.0	8.0, 18.0	5.5, 16.5
Min, Max	0.0, 32.0	5.0, 40.0	0.0, 40.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-rbc24.sas V.03.05 Output file: t-rbc24-nti.pdf 24AUG2023:17:07

Table 2.2602: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
Duration of the RT phase (months) in stratum 2			
N	17	11	28
Mean (SD)	4.64 (1.641)	4.75 (1.768)	4.68 (1.660)
Median	5.52	5.55	5.54
Q1, Q3	4.67, 5.55	5.32, 5.55	4.98, 5.55
Min, Max	0.92, 5.78	0.66, 5.78	0.66, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

Table 2.2602: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
Stratum 3			
Transfusion Dependence at Baseline = 'No' and TSS < 18 at Baseline			
RBC transfusion Rate in RT phase (units/month)			
N	5	2	7
Mean (SD)	1.3 (1.31)	0.5 (0.64)	1.0 (1.17)
Median	1.0	0.5	0.9
Q1, Q3	0.2, 2.0	0.0, 0.9	0.0, 2.0
Min, Max	0.0, 3.1	0.0, 0.9	0.0, 3.1
Negative Binomial Model			
Rate of RBC transfusion with 95% CI (units/month)	1.19 (0.38, 3.73)	0.48 (0.08, 3.01)	
Ratio of Rate for RBC Transfusion with 95% CI	2.48 (0.28, 21.56)	-	-
Proportional Means Model - Supportive Analysis			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	1.71 (0.34, 8.46)	-	-
Total number of RBC transfusion in stratum 3 in RT phase			
N	5	2	7
Mean (SD)	3.8 (4.15)	2.5 (3.54)	3.4 (3.74)
Median	2.0	2.5	2.0
Q1, Q3	1.0, 6.0	0.0, 5.0	0.0, 6.0
Min, Max	0.0, 10.0	0.0, 5.0	0.0, 10.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

Table 2.2602: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
Duration of the RT phase (months) in stratum 3			
N	5	2	7
Mean (SD)	4.25 (2.108)	4.47 (1.533)	4.31 (1.834)
Median	5.55	4.47	5.55
Q1, Q3	3.19, 5.72	3.38, 5.55	3.19, 5.72
Min, Max	1.02, 5.78	3.38, 5.55	1.02, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

Table 2.2602: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
Stratum 4			
Transfusion Dependence at Baseline = 'No' and TSS >= 18 at Baseline			
RBC transfusion Rate in RT phase (units/month)			
N	4	3	7
Mean (SD)	1.8 (1.25)	1.5 (1.02)	1.6 (1.07)
Median	2.0	1.8	1.9
Q1, Q3	1.0, 2.6	0.4, 2.3	0.4, 2.3
Min, Max	0.0, 2.9	0.4, 2.3	0.0, 2.9
Negative Binomial Model			
Rate of RBC transfusion with 95% CI (units/month)	2.12 (1.35, 3.35)	1.49 (0.89, 2.51)	
Ratio of Rate for RBC Transfusion with 95% CI	1.42 (0.71, 2.85)	-	-
Proportional Means Model - Supportive Analysis			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	1.49 (0.74, 2.97)	-	-
Total number of RBC transfusion in stratum 4 in RT phase			
N	4	3	7
Mean (SD)	10.0 (7.16)	8.3 (5.69)	9.3 (6.10)
Median	11.5	10.0	11.0
Q1, Q3	5.5, 14.5	2.0, 13.0	2.0, 13.0
Min, Max	0.0, 17.0	2.0, 13.0	0.0, 17.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

Table 2.2602: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are not Transfusion Independent at Baseline

	MMB (N=61)	BAT (N=30)	Total (N=91)
Duration of the RT phase (months) in stratum 4			
N	4	3	7
Mean (SD)	4.52 (2.379)	5.59 (0.057)	4.98 (1.777)
Median	5.67	5.55	5.55
Q1, Q3	3.25, 5.78	5.55, 5.65	5.55, 5.78
Min, Max	0.95, 5.78	5.55, 5.65	0.95, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

Table 2.2603: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	MMB (N=52)	BAT (N=25)	Total (N=77)
All Strata Combined			
RBC transfusion Rate in RT phase (units/month)			
N	52	25	77
Mean (SD)	2.3 (2.26)	2.7 (2.08)	2.4 (2.20)
Median	1.6	1.8	1.8
Q1, Q3	0.4, 3.9	1.1, 3.2	0.7, 3.8
Min, Max	0.0, 8.2	0.0, 7.6	0.0, 8.2
Negative Binomial Model			
Adjusted for Strata			
Rate of RBC transfusion with 95% CI (units/month)	2.43 (1.82, 3.24)	2.61 (1.75, 3.89)	
Ratio of Rate for RBC Transfusion with 95% CI	0.93 (0.57, 1.52)	-	-
p-value	0.78	-	-
Unadjusted for Strata			
Rate of RBC transfusion with 95% CI (units/month)	2.29 (1.73, 3.02)	2.62 (1.74, 3.93)	
Ratio of Rate for RBC Transfusion with 95% CI	0.87 (0.53, 1.43)	-	-
p-value	0.59	-	-
Proportional Means Model - Supportive Analysis			
Stratified			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.92 (0.63, 1.34)	-	-
p-value	0.66	-	-
Unstratified			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.89 (0.60, 1.31)	-	-
p-value	0.55	-	-

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-rbc24-td.sas V.03.05 Output file: t-rbc24-td.pdf 24AUG2023:17:07

Table 2.2603: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	MMB (N=52)	BAT (N=25)	Total (N=77)
Total number of RBC transfusion unit in RT phase			
N	52	25	77
Mean (SD)	10.8 (10.85)	11.6 (8.68)	11.1 (10.15)
Median	7.5	8.0	8.0
Q1, Q3	2.0, 16.0	6.0, 16.0	4.0, 16.0
Min, Max	0.0, 38.0	0.0, 40.0	0.0, 40.0
Duration of the RT phase (months)			
N	52	25	77
Mean (SD)	5.06 (1.192)	4.87 (1.691)	5.00 (1.365)
Median	5.55	5.55	5.55
Q1, Q3	5.44, 5.65	5.42, 5.65	5.42, 5.65
Min, Max	0.92, 5.78	0.43, 5.78	0.43, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

Table 2.2603: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	MMB (N=52)	BAT (N=25)	Total (N=77)
Stratum 1			
Transfusion Dependence at Baseline = 'Yes' and TSS < 18 at Baseline			
RBC transfusion Rate in RT phase (units/month)			
N	35	14	49
Mean (SD)	2.1 (2.14)	2.0 (1.50)	2.0 (1.96)
Median	1.0	1.3	1.3
Q1, Q3	0.4, 3.3	0.9, 3.0	0.5, 3.1
Min, Max	0.0, 6.8	0.0, 5.0	0.0, 6.8
Negative Binomial Model			
Rate of RBC transfusion with 95% CI (units/month)	2.05 (1.44, 2.91)	2.03 (1.15, 3.57)	
Ratio of Rate for RBC Transfusion with 95% CI	1.01 (0.52, 1.97)	-	-
Proportional Means Model - Supportive Analysis			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	1.02 (0.63, 1.66)	-	-
Total number of RBC transfusion in stratum 1 in RT phase			
N	35	14	49
Mean (SD)	10.6 (11.47)	9.8 (7.06)	10.4 (10.33)
Median	6.0	7.5	7.0
Q1, Q3	2.0, 16.0	5.0, 16.0	2.0, 16.0
Min, Max	0.0, 38.0	0.0, 25.0	0.0, 38.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

Table 2.2603: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	MMB (N=52)	BAT (N=25)	Total (N=77)
Duration of the RT phase (months) in stratum 1			
N	35	14	49
Mean (SD)	5.27 (0.854)	4.96 (1.690)	5.18 (1.145)
Median	5.55	5.55	5.55
Q1, Q3	5.49, 5.72	5.49, 5.75	5.49, 5.72
Min, Max	2.14, 5.78	0.43, 5.78	0.43, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

Table 2.2603: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	MMB (N=52)	BAT (N=25)	Total (N=77)
Stratum 2			
Transfusion Dependence at Baseline = 'Yes' and TSS >= 18 at Baseline			
RBC transfusion Rate in RT phase (units/month)			
N	17	11	28
Mean (SD)	2.9 (2.47)	3.5 (2.45)	3.1 (2.44)
Median	2.2	2.5	2.4
Q1, Q3	0.7, 4.5	1.4, 6.2	1.3, 5.2
Min, Max	0.0, 8.2	1.0, 7.6	0.0, 8.2
Negative Binomial Model			
Rate of RBC transfusion with 95% CI (units/month)	2.79 (1.80, 4.32)	3.37 (1.96, 5.80)	
Ratio of Rate for RBC Transfusion with 95% CI	0.83 (0.41, 1.66)	-	-
Proportional Means Model - Supportive Analysis			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.81 (0.45, 1.45)	-	-
Total number of RBC transfusion in stratum 2 in RT phase			
N	17	11	28
Mean (SD)	11.2 (9.78)	14.0 (10.25)	12.3 (9.88)
Median	9.0	10.0	10.0
Q1, Q3	4.0, 16.0	8.0, 18.0	5.5, 16.5
Min, Max	0.0, 32.0	5.0, 40.0	0.0, 40.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

Table 2.2603: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Dependent at Baseline

	MMB (N=52)	BAT (N=25)	Total (N=77)
Duration of the RT phase (months) in stratum 2			
N	17	11	28
Mean (SD)	4.64 (1.641)	4.75 (1.768)	4.68 (1.660)
Median	5.52	5.55	5.54
Q1, Q3	4.67, 5.55	5.32, 5.55	4.98, 5.55
Min, Max	0.92, 5.78	0.66, 5.78	0.66, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

Table 2.2601: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=5)	BAT (N=9)	Total (N=14)
All Strata Combined			
RBC transfusion Rate in RT phase (units/month)			
N	5	9	14
Mean (SD)	0.8 (1.06)	0.6 (0.87)	0.7 (0.91)
Median	0.2	0.0	0.1
Q1, Q3	0.0, 1.9	0.0, 0.7	0.0, 1.6
Min, Max	0.0, 2.1	0.0, 2.4	0.0, 2.4
Negative Binomial Model			
Adjusted for Strata			
Rate of RBC transfusion with 95% CI (units/month)	0.78 (0.14, 4.35)	0.54 (0.16, 1.89)	
Ratio of Rate for RBC Transfusion with 95% CI	1.43 (0.17, 11.86)	-	-
p-value	0.74	-	-
Unadjusted for Strata			
Rate of RBC transfusion with 95% CI (units/month)	0.78 (0.14, 4.29)	0.54 (0.16, 1.88)	
Ratio of Rate for RBC Transfusion with 95% CI	1.43 (0.17, 11.83)	-	-
p-value	0.74	-	-
Proportional Means Model - Supportive Analysis			
Stratified			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	1.18 (0.28, 5.01)	-	-
p-value	0.82	-	-
Unstratified			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	1.13 (0.25, 5.15)	-	-
p-value	0.87	-	-

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

Table 2.2601: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=5)	BAT (N=9)	Total (N=14)
Total number of RBC transfusion unit in RT phase			
N	5	9	14
Mean (SD)	2.0 (2.92)	2.2 (3.19)	2.1 (2.98)
Median	1.0	0.0	0.5
Q1, Q3	0.0, 2.0	0.0, 4.0	0.0, 4.0
Min, Max	0.0, 7.0	0.0, 9.0	0.0, 9.0
Duration of the RT phase (months)			
N	5	9	14
Mean (SD)	3.95 (1.858)	4.85 (1.458)	4.53 (1.603)
Median	4.14	5.55	5.49
Q1, Q3	3.68, 5.49	5.49, 5.59	3.68, 5.55
Min, Max	0.95, 5.49	2.10, 5.72	0.95, 5.72

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-rbc24-ti.sas V.03.05 Output file: t-rbc24-ti.pdf 24AUG2023:17:06

Table 2.2601: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=5)	BAT (N=9)	Total (N=14)
Stratum 3			
Transfusion Dependence at Baseline = 'No' and TSS < 18 at Baseline			
RBC transfusion Rate in RT phase (units/month)			
N	2	4	6
Mean (SD)	1.0 (1.48)	0.5 (0.77)	0.7 (0.94)
Median	1.0	0.2	0.2
Q1, Q3	0.0, 2.1	0.0, 1.0	0.0, 1.6
Min, Max	0.0, 2.1	0.0, 1.6	0.0, 2.1
Negative Binomial Model			
Rate of RBC transfusion with 95% CI (units/month)	0.92 (0.05, 16.00)	0.50 (0.08, 3.09)	
Ratio of Rate for RBC Transfusion with 95% CI	1.85 (0.06, 55.10)	-	-
Proportional Means Model - Supportive Analysis			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.77 (0.06, 9.79)	-	-
Total number of RBC transfusion in stratum 3 in RT phase			
N	2	4	6
Mean (SD)	1.0 (1.41)	2.8 (4.27)	2.2 (3.49)
Median	1.0	1.0	1.0
Q1, Q3	0.0, 2.0	0.0, 5.5	0.0, 2.0
Min, Max	0.0, 2.0	0.0, 9.0	0.0, 9.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

Table 2.2601: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=5)	BAT (N=9)	Total (N=14)
Duration of the RT phase (months) in stratum 3			
N	2	4	6
Mean (SD)	3.22 (3.206)	5.59 (0.097)	4.80 (1.885)
Median	3.22	5.57	5.52
Q1, Q3	0.95, 5.49	5.52, 5.65	5.49, 5.59
Min, Max	0.95, 5.49	5.49, 5.72	0.95, 5.72

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

Table 2.2601: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=5)	BAT (N=9)	Total (N=14)
Stratum 4			
Transfusion Dependence at Baseline = 'No' and TSS >= 18 at Baseline			
RBC transfusion Rate in RT phase (units/month)			
N	3	5	8
Mean (SD)	0.7 (1.04)	0.6 (1.03)	0.7 (0.96)
Median	0.2	0.0	0.1
Q1, Q3	0.0, 1.9	0.0, 0.7	0.0, 1.3
Min, Max	0.0, 1.9	0.0, 2.4	0.0, 2.4
Negative Binomial Model			
Rate of RBC transfusion with 95% CI (units/month)	0.70 (0.09, 5.69)	0.58 (0.11, 3.15)	
Ratio of Rate for RBC Transfusion with 95% CI	1.21 (0.08, 17.70)	-	-
Proportional Means Model - Supportive Analysis			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	1.43 (0.25, 8.26)	-	-
Total number of RBC transfusion in stratum 4 in RT phase			
N	3	5	8
Mean (SD)	2.7 (3.79)	1.8 (2.49)	2.1 (2.80)
Median	1.0	0.0	0.5
Q1, Q3	0.0, 7.0	0.0, 4.0	0.0, 4.5
Min, Max	0.0, 7.0	0.0, 5.0	0.0, 7.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

Table 2.2601: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set Who are Transfusion Independent at Baseline

	MMB (N=5)	BAT (N=9)	Total (N=14)
Duration of the RT phase (months) in stratum 4			
N	3	5	8
Mean (SD)	4.44 (0.939)	4.26 (1.807)	4.32 (1.458)
Median	4.14	5.55	4.81
Q1, Q3	3.68, 5.49	2.46, 5.55	3.07, 5.55
Min, Max	3.68, 5.49	2.10, 5.62	2.10, 5.62

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-rbc24-ti.sas V.03.05 Output file: t-rbc24-ti.pdf 24AUG2023:17:06

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Table 2.2402: Analysis of Rate of RBC Transfusion by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
RBC transfusion Rate in RT phase (units/month)					
N	24	9	42	30	
Mean (SD)	1.9 (1.69)	2.0 (2.26)	2.2 (2.34)	2.0 (1.92)	
Median	1.9	1.8	1.4	1.4	
Q1, Q3	0.4, 3.1	1.1, 1.8	0.3, 3.3	0.5, 3.0	
Min, Max	0.0, 6.0	0.0, 7.6	0.0, 8.2	0.0, 7.2	
Negative Binomial Model					
Adjusted for Strata					
Rate of RBC transfusion with 95% CI (units/month)	1.48 (0.90, 2.42)	1.12 (0.52, 2.43)	1.54 (1.02, 2.32)	1.46 (0.95, 2.23)	
Ratio of Rate for RBC Transfusion with 95% CI	1.31 (0.53, 3.23)	-	1.06 (0.63, 1.78)	-	
p-value	0.55	-	0.83	-	
Adjusted interaction test for Treatment*Age Group [1]	-	-	-	-	0.83
Unadjusted for Strata					
Rate of RBC transfusion with 95% CI (units/month)	1.85 (1.17, 2.95)	1.74 (0.78, 3.91)	2.21 (1.55, 3.13)	1.98 (1.31, 3.00)	
Ratio of Rate for RBC Transfusion with 95% CI	1.06 (0.42, 2.70)	-	1.11 (0.65, 1.92)	-	
p-value	0.90	-	0.70	-	
Unadjusted interaction test for Treatment*Age Group [1]	-	-	-	-	0.93

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-sg-rbc-rt-csr.sas V.03.05 Output file: t-rbc-rt-csr-age.pdf 24AUG2023:17:05

Table 2.2402: Analysis of Rate of RBC Transfusion by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Proportional Means Model - Supportive Analysis					
Stratified					
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	1.36 (0.89, 2.07)	-	0.91 (0.59, 1.41)	-	
p-value	0.16	-	0.68	-	
Unstratified					
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	1.30 (0.76, 2.22)	-	1.09 (0.68, 1.73)	-	
p-value	0.34	-	0.73	-	
Total number of RBC transfusion unit in RT phase					
N	24	9	42	30	
Mean (SD)	8.6 (8.23)	5.9 (3.92)	10.1 (11.27)	9.6 (9.13)	
Median	6.5	6.0	6.0	8.0	
Q1, Q3	1.0, 13.5	5.0, 10.0	2.0, 13.0	3.0, 14.0	
Min, Max	0.0, 28.0	0.0, 10.0	0.0, 38.0	0.0, 40.0	
Duration of the RT phase (months)					
N	24	9	42	30	
Mean (SD)	4.85 (1.326)	4.27 (1.960)	4.91 (1.474)	5.08 (1.371)	
Median	5.50	5.42	5.55	5.55	
Q1, Q3	3.98, 5.73	2.46, 5.55	5.42, 5.62	5.49, 5.62	
Min, Max	0.95, 5.78	0.66, 5.72	0.92, 5.78	0.43, 5.78	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell.

Data Extracted: CRF data: 25JUN2019

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Table 2.2407: Analysis of Rate of RBC Transfusion by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8g/dL		HGB >=8g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
RBC transfusion Rate in RT phase (units/month)					
N	27	6	39	33	
Mean (SD)	2.5 (2.46)	3.7 (2.69)	1.8 (1.82)	1.7 (1.69)	
Median	1.3	3.0	1.7	1.4	
Q1, Q3	0.5, 4.5	1.1, 6.2	0.0, 2.9	0.4, 2.4	
Min, Max	0.0, 8.2	1.0, 7.6	0.0, 6.8	0.0, 7.2	
Negative Binomial Model					
Adjusted for Strata					
Rate of RBC transfusion with 95% CI (units/month)	2.54 (1.74, 3.70)	3.32 (1.49, 7.39)	1.60 (1.08, 2.37)	1.34 (0.89, 2.02)	
Ratio of Rate for RBC Transfusion with 95% CI	0.76 (0.32, 1.85)	-	1.19 (0.69, 2.07)	-	
p-value	0.55	-	0.54	-	
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [1]	-	-	-	-	0.40
Unadjusted for Strata					
Rate of RBC transfusion with 95% CI (units/month)	2.47 (1.69, 3.60)	3.41 (1.49, 7.81)	1.80 (1.22, 2.65)	1.69 (1.11, 2.57)	
Ratio of Rate for RBC Transfusion with 95% CI	0.72 (0.29, 1.80)	-	1.07 (0.60, 1.89)	-	
p-value	0.49	-	0.82	-	
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [1]	-	-	-	-	0.49

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-sg-rbc-rt-csr.sas V.03.05 Output file: t-rbc-rt-csr-hgb.pdf 24AUG2023:17:05

Table 2.2407: Analysis of Rate of RBC Transfusion by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8g/dL		HGB >=8g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Proportional Means Model - Supportive Analysis					
Stratified					
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.92 (0.52, 1.62)	-	1.03 (0.66, 1.59)	-	
p-value	0.76	-	0.91	-	
Unstratified					
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.91 (0.52, 1.59)	-	1.04 (0.64, 1.69)	-	
p-value	0.73	-	0.87	-	
Total number of RBC transfusion unit in RT phase					
N	27	6	39	33	
Mean (SD)	11.0 (10.94)	10.3 (5.61)	8.6 (9.72)	8.5 (8.77)	
Median	6.0	8.5	6.0	7.0	
Q1, Q3	2.0, 16.0	6.0, 16.0	0.0, 12.0	2.0, 10.0	
Min, Max	0.0, 38.0	5.0, 18.0	0.0, 38.0	0.0, 40.0	
Duration of the RT phase (months)					
N	27	6	39	33	
Mean (SD)	4.88 (1.398)	4.15 (2.303)	4.89 (1.440)	5.03 (1.362)	
Median	5.55	5.44	5.52	5.55	
Q1, Q3	4.67, 5.65	1.77, 5.78	5.29, 5.68	5.49, 5.59	
Min, Max	0.92, 5.78	0.66, 5.78	0.95, 5.78	0.43, 5.78	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell.

Table 2.2406: Analysis of Rate of RBC Transfusion by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
RBC transfusion Rate in RT phase (units/month)					
N	49	31	17	8	
Mean (SD)	2.0 (2.03)	1.8 (1.86)	2.4 (2.41)	2.5 (2.43)	
Median	1.3	1.4	2.0	1.8	
Q1, Q3	0.4, 2.9	0.5, 2.5	0.0, 3.3	0.7, 3.8	
Min, Max	0.0, 8.2	0.0, 7.6	0.0, 6.6	0.0, 7.2	
Negative Binomial Model					
Adjusted for Strata					
Rate of RBC transfusion with 95% CI (units/month)	1.42 (0.99, 2.04)	1.37 (0.93, 2.01)	1.88 (1.03, 3.43)	1.65 (0.63, 4.32)	
Ratio of Rate for RBC Transfusion with 95% CI	1.04 (0.64, 1.69)	-	1.14 (0.40, 3.26)	-	
p-value	0.88	-	0.81	-	
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [1]	-	-	-	-	0.75
Unadjusted for Strata					
Rate of RBC transfusion with 95% CI (units/month)	1.97 (1.44, 2.70)	1.74 (1.16, 2.61)	2.37 (1.30, 4.33)	2.59 (1.09, 6.16)	
Ratio of Rate for RBC Transfusion with 95% CI	1.13 (0.68, 1.89)	-	0.92 (0.32, 2.62)	-	
p-value	0.63	-	0.87	-	
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [1]	-	-	-	-	0.70

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-sg-rbc-rt-csr.sas V.03.05 Output file: t-rbc-rt-csr-ip2.pdf 24AUG2023:17:05

Table 2.2406: Analysis of Rate of RBC Transfusion by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Proportional Means Model - Supportive Analysis					
Stratified					
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	1.04 (0.72, 1.51)	-	0.93 (0.44, 1.96)	-	
p-value	0.82	-	0.85	-	
Unstratified					
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	1.20 (0.80, 1.80)	-	0.86 (0.39, 1.91)	-	
p-value	0.37	-	0.71	-	
Total number of RBC transfusion unit in RT phase					
N	49	31	17	8	
Mean (SD)	9.3 (9.29)	7.5 (6.13)	10.4 (12.83)	13.8 (13.41)	
Median	6.0	7.0	4.0	10.0	
Q1, Q3	2.0, 13.0	3.0, 10.0	0.0, 13.0	4.0, 21.0	
Min, Max	0.0, 38.0	0.0, 25.0	0.0, 38.0	0.0, 40.0	
Duration of the RT phase (months)					
N	49	31	17	8	
Mean (SD)	5.06 (1.201)	4.89 (1.489)	4.38 (1.845)	4.93 (1.827)	
Median	5.55	5.55	5.52	5.55	
Q1, Q3	5.45, 5.72	5.42, 5.62	3.19, 5.59	5.40, 5.67	
Min, Max	0.95, 5.78	0.66, 5.78	0.92, 5.75	0.43, 5.78	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell.

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Table 2.2405: Analysis of Rate of RBC Transfusion by Baseline DIPSS Three-Level Risk

Randomized Treatment Phase

ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
RBC transfusion Rate in RT phase (units/month)				
N	5	7	44	24
Mean (SD)	1.8 (2.38)	2.4 (2.44)	2.0 (2.01)	1.7 (1.68)
Median	0.5	1.8	1.4	1.4
Q1, Q3	0.0, 3.3	0.9, 3.2	0.4, 2.9	0.2, 2.5
Min, Max	0.0, 5.3	0.5, 7.6	0.0, 8.2	0.0, 6.2
Negative Binomial Model				
Adjusted for Strata				
Rate of RBC transfusion with 95% CI (units/month)	0.00 (0.00, Inf.)	0.00 (0.00, Inf.)	1.48 (1.01, 2.16)	1.45 (0.94, 2.24)
Ratio of Rate for RBC Transfusion with 95% CI	3.91 (1.72, 8.87)	-	1.02 (0.59, 1.76)	-
p-value	0.001	-	0.95	-
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [1]	-	-	-	-
Unadjusted for Strata				
Rate of RBC transfusion with 95% CI (units/month)	1.84 (0.68, 4.99)	2.19 (0.89, 5.35)	1.99 (1.43, 2.77)	1.63 (1.03, 2.56)
Ratio of Rate for RBC Transfusion with 95% CI	0.84 (0.22, 3.22)	-	1.22 (0.70, 2.14)	-
p-value	0.80	-	0.48	-
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [1]	-	-	-	-

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Proportional means model is Andersen-Gill model with robust sandwich variance estimate.

[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

RBC = Red Blood Cell. Inf. = Infinite.

Data Extracted: CRF data: 25JUN2019

Table 2.2405: Analysis of Rate of RBC Transfusion by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=17)	High Risk BAT (N=8)	p-value
RBC transfusion Rate in RT phase (units/month)			
N	17	8	
Mean (SD)	2.4 (2.41)	2.5 (2.43)	
Median	2.0	1.8	
Q1, Q3	0.0, 3.3	0.7, 3.8	
Min, Max	0.0, 6.6	0.0, 7.2	
Negative Binomial Model			
Adjusted for Strata			
Rate of RBC transfusion with 95% CI (units/month)	1.88 (1.03, 3.43)	1.65 (0.63, 4.32)	
Ratio of Rate for RBC Transfusion with 95% CI	1.14 (0.40, 3.26)	-	
p-value	0.81	-	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [1]	-	-	0.91
Unadjusted for Strata			
Rate of RBC transfusion with 95% CI (units/month)	2.37 (1.30, 4.33)	2.59 (1.09, 6.16)	
Ratio of Rate for RBC Transfusion with 95% CI	0.92 (0.32, 2.62)	-	
p-value	0.87	-	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [1]	-	-	0.81

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell. Inf. = Infinite.

Data Extracted: CRF data: 25JUN2019

Table 2.2405: Analysis of Rate of RBC Transfusion by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Proportional Means Model - Supportive Analysis				
Stratified				
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	4.22 (2.53, 7.03)	-	0.96 (0.63, 1.48)	-
p-value	< 0.001	-	0.86	-
Unstratified				
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	1.19 (0.40, 3.54)	-	1.23 (0.78, 1.94)	-
p-value	0.75	-	0.38	-
Total number of RBC transfusion unit in RT phase				
N	5	7	44	24
Mean (SD)	9.6 (13.28)	8.1 (5.08)	9.2 (8.94)	7.3 (6.48)
Median	1.0	6.0	6.5	7.5
Q1, Q3	0.0, 18.0	5.0, 10.0	2.0, 12.5	1.0, 10.5
Min, Max	0.0, 29.0	3.0, 18.0	0.0, 38.0	0.0, 25.0
Duration of the RT phase (months)				
N	5	7	44	24
Mean (SD)	4.82 (1.499)	4.81 (1.835)	5.09 (1.180)	4.91 (1.417)
Median	5.49	5.49	5.55	5.55
Q1, Q3	5.49, 5.49	5.32, 5.55	5.37, 5.73	5.50, 5.63
Min, Max	2.14, 5.49	0.66, 5.68	0.95, 5.78	1.61, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell. Inf. = Infinite.

Data Extracted: CRF data: 25JUN2019

Table 2.2405: Analysis of Rate of RBC Transfusion by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=17)	High Risk BAT (N=8)	p-value
Proportional Means Model - Supportive Analysis			
Stratified			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.93 (0.44, 1.96)	-	
p-value	0.85	-	
Unstratified			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.86 (0.39, 1.91)	-	
p-value	0.71	-	
Total number of RBC transfusion unit in RT phase			
N	17	8	
Mean (SD)	10.4 (12.83)	13.8 (13.41)	
Median	4.0	10.0	
Q1, Q3	0.0, 13.0	4.0, 21.0	
Min, Max	0.0, 38.0	0.0, 40.0	
Duration of the RT phase (months)			
N	17	8	
Mean (SD)	4.38 (1.845)	4.93 (1.827)	
Median	5.52	5.55	
Q1, Q3	3.19, 5.59	5.40, 5.67	
Min, Max	0.92, 5.75	0.43, 5.78	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell. Inf. = Infinite.

Table 2.2408: Analysis of Rate of RBC Transfusion by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
RBC transfusion Rate in RT phase (units/month)				
N	45	23	13	8
Mean (SD)	2.1 (2.22)	2.2 (2.05)	2.3 (2.20)	1.7 (1.84)
Median	1.7	1.6	2.2	1.4
Q1, Q3	0.3, 3.1	0.7, 2.9	0.2, 3.8	0.0, 3.1
Min, Max	0.0, 8.2	0.0, 7.6	0.0, 6.0	0.0, 4.5
Negative Binomial Model				
Adjusted for Strata				
Rate of RBC transfusion with 95% CI (units/month)	1.72 (1.18, 2.51)	1.60 (0.99, 2.60)	0.00 (0.00, Inf.)	0.00 (0.00, Inf.)
Ratio of Rate for RBC Transfusion with 95% CI	1.07 (0.61, 1.90)	-	1.29 (0.49, 3.40)	-
p-value	0.80	-	0.61	-
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [1]	-	-	-	-
Unadjusted for Strata				
Rate of RBC transfusion with 95% CI (units/month)	2.14 (1.52, 2.99)	2.07 (1.28, 3.34)	2.30 (1.16, 4.57)	1.80 (0.75, 4.31)
Ratio of Rate for RBC Transfusion with 95% CI	1.03 (0.57, 1.86)	-	1.28 (0.42, 3.90)	-
p-value	0.92	-	0.66	-
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [1]	-	-	-	-

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell. Inf. = Infinite.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-sg-rbc-rt-csr.sas V.03.05 Output file: t-rbc-rt-csr-mf.pdf 24AUG2023:17:05

Table 2.2408: Analysis of Rate of RBC Transfusion by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=8)	Post-PV Myelofibrosis BAT (N=8)	p-value
RBC transfusion Rate in RT phase (units/month)			
N	8	8	
Mean (SD)	1.4 (1.33)	1.7 (2.04)	
Median	1.0	1.1	
Q1, Q3	0.6, 2.0	0.4, 2.4	
Min, Max	0.0, 4.2	0.0, 6.2	
Negative Binomial Model			
Adjusted for Strata			
Rate of RBC transfusion with 95% CI (units/month)	0.89 (0.44, 1.81)	1.42 (0.71, 2.83)	
Ratio of Rate for RBC Transfusion with 95% CI	0.63 (0.23, 1.70)	-	
p-value	0.36	-	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [1]	-	-	0.87
Unadjusted for Strata			
Rate of RBC transfusion with 95% CI (units/month)	1.41 (0.69, 2.87)	1.63 (0.79, 3.36)	
Ratio of Rate for RBC Transfusion with 95% CI	0.87 (0.31, 2.39)	-	
p-value	0.78	-	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [1]	-	-	0.88

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell. Inf. = Infinite.

Data Extracted: CRF data: 25JUN2019

Table 2.2408: Analysis of Rate of RBC Transfusion by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Proportional Means Model - Supportive Analysis				
Stratified				
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	1.08 (0.70, 1.67)	-	1.02 (0.47, 2.21)	-
p-value	0.74	-	0.96	-
Unstratified				
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	1.11 (0.69, 1.80)	-	0.95 (0.42, 2.16)	-
p-value	0.67	-	0.91	-
Total number of RBC transfusion unit in RT phase				
N	45	23	13	8
Mean (SD)	10.1 (11.09)	9.2 (8.64)	9.3 (9.62)	9.4 (10.18)
Median	7.0	6.0	6.0	8.0
Q1, Q3	1.0, 15.0	4.0, 14.0	1.0, 12.0	0.0, 17.0
Min, Max	0.0, 38.0	0.0, 40.0	0.0, 28.0	0.0, 25.0
Duration of the RT phase (months)				
N	45	23	13	8
Mean (SD)	4.87 (1.446)	4.94 (1.474)	4.71 (1.638)	4.56 (2.002)
Median	5.55	5.55	5.55	5.55
Q1, Q3	5.29, 5.62	5.42, 5.59	4.70, 5.72	3.89, 5.70
Min, Max	0.95, 5.78	0.66, 5.78	0.92, 5.78	0.43, 5.75

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell. Inf. = Infinite.

Table 2.2408: Analysis of Rate of RBC Transfusion by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=8)	Post-PV Myelofibrosis BAT (N=8)	p-value
Proportional Means Model - Supportive Analysis			
Stratified			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.64 (0.33, 1.26)	-	
p-value	0.20	-	
Unstratified			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.99 (0.44, 2.21)	-	
p-value	0.98	-	
Total number of RBC transfusion unit in RT phase			
N	8	8	
Mean (SD)	7.0 (5.48)	6.8 (5.70)	
Median	5.5	6.0	
Q1, Q3	3.0, 11.5	2.0, 10.5	
Min, Max	0.0, 16.0	0.0, 17.0	
Duration of the RT phase (months)			
N	8	8	
Mean (SD)	5.23 (0.756)	5.10 (1.348)	
Median	5.55	5.55	
Q1, Q3	4.90, 5.67	5.52, 5.60	
Min, Max	3.81, 5.78	1.77, 5.72	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell. Inf. = Infinite.

Data Extracted: CRF data: 25JUN2019

Table 2.2404: Analysis of Rate of RBC Transfusion by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
RBC transfusion Rate in RT phase (units/month)					
N	29	7	37	32	
Mean (SD)	1.6 (1.81)	1.9 (2.62)	2.5 (2.28)	2.0 (1.86)	
Median	1.0	1.1	1.9	1.4	
Q1, Q3	0.0, 2.2	0.0, 3.1	0.5, 4.2	0.7, 2.7	
Min, Max	0.0, 6.6	0.0, 7.2	0.0, 8.2	0.0, 7.6	
Negative Binomial Model					
Adjusted for Strata					
Rate of RBC transfusion with 95% CI (units/month)	1.07 (0.50, 2.28)	1.22 (0.34, 4.32)	1.90 (1.38, 2.63)	1.49 (1.06, 2.09)	
Ratio of Rate for RBC Transfusion with 95% CI	0.88 (0.25, 3.07)	-	1.28 (0.82, 1.99)	-	
p-value	0.84	-	0.27	-	
Adjusted interaction test for Treatment*Region [1]	-	-	-	-	0.60
Unadjusted for Strata					
Rate of RBC transfusion with 95% CI (units/month)	1.58 (0.93, 2.67)	2.00 (0.69, 5.77)	2.47 (1.78, 3.42)	1.89 (1.32, 2.71)	
Ratio of Rate for RBC Transfusion with 95% CI	0.79 (0.24, 2.58)	-	1.31 (0.80, 2.13)	-	
p-value	0.70	-	0.28	-	
Unadjusted interaction test for Treatment*Region [1]	-	-	-	-	0.35

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell.

Table 2.2404: Analysis of Rate of RBC Transfusion by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Proportional Means Model - Supportive Analysis					
Stratified					
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.55 (0.24, 1.27)	-	1.28 (0.90, 1.83)	-	
p-value	0.16	-	0.17	-	
Unstratified					
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.69 (0.25, 1.87)	-	1.36 (0.90, 2.03)	-	
p-value	0.46	-	0.14	-	
Total number of RBC transfusion unit in RT phase					
N	29	7	37	32	
Mean (SD)	7.5 (9.46)	10.6 (14.59)	11.2 (10.63)	8.3 (6.55)	
Median	6.0	6.0	9.0	7.5	
Q1, Q3	0.0, 11.0	0.0, 18.0	2.0, 17.0	4.0, 12.0	
Min, Max	0.0, 38.0	0.0, 40.0	0.0, 38.0	0.0, 25.0	
Duration of the RT phase (months)					
N	29	7	37	32	
Mean (SD)	4.93 (1.403)	4.80 (1.934)	4.85 (1.437)	4.92 (1.474)	
Median	5.55	5.55	5.55	5.55	
Q1, Q3	5.45, 5.55	5.32, 5.55	4.67, 5.72	5.49, 5.63	
Min, Max	0.95, 5.78	0.43, 5.78	0.92, 5.78	0.66, 5.78	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell.

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Table 2.2403: Analysis of Rate of RBC Transfusion by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
RBC transfusion Rate in RT phase (units/month)					
N	52	18	14	21	
Mean (SD)	2.1 (1.95)	2.2 (1.95)	2.3 (2.74)	1.8 (2.02)	
Median	1.8	1.5	0.7	1.3	
Q1, Q3	0.3, 3.2	0.7, 2.9	0.4, 4.7	0.4, 2.5	
Min, Max	0.0, 6.8	0.0, 7.6	0.0, 8.2	0.0, 7.2	
Negative Binomial Model					
Adjusted for Strata					
Rate of RBC transfusion with 95% CI (units/month)	1.67 (1.19, 2.36)	1.72 (1.02, 2.89)	1.00 (0.52, 1.94)	1.06 (0.65, 1.74)	
Ratio of Rate for RBC Transfusion with 95% CI	0.97 (0.54, 1.74)	-	0.94 (0.45, 1.98)	-	
p-value	0.92	-	0.88	-	
Adjusted interaction test for Treatment*Gender [1]	-	-	-	-	0.87
Unadjusted for Strata					
Rate of RBC transfusion with 95% CI (units/month)	2.05 (1.52, 2.75)	2.08 (1.24, 3.49)	2.19 (1.11, 4.35)	1.81 (1.04, 3.15)	
Ratio of Rate for RBC Transfusion with 95% CI	0.99 (0.54, 1.79)	-	1.21 (0.50, 2.93)	-	
p-value	0.97	-	0.67	-	
Unadjusted interaction test for Treatment*Gender [1]	-	-	-	-	0.69

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell.

Data Extracted: CRF data: 25JUN2019

Table 2.2403: Analysis of Rate of RBC Transfusion by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Proportional Means Model - Supportive Analysis					
Stratified					
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	1.06 (0.70, 1.60)	-	0.85 (0.42, 1.72)	-	
p-value	0.78	-	0.65	-	
Unstratified					
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	1.10 (0.72, 1.69)	-	1.02 (0.48, 2.20)	-	
p-value	0.66	-	0.96	-	
Total number of RBC transfusion unit in RT phase					
N	52	18	14	21	
Mean (SD)	9.8 (10.30)	8.4 (6.37)	8.8 (10.26)	9.0 (9.86)	
Median	6.5	7.0	4.0	7.0	
Q1, Q3	1.0, 14.0	4.0, 13.0	2.0, 13.0	2.0, 11.0	
Min, Max	0.0, 38.0	0.0, 24.0	0.0, 32.0	0.0, 40.0	
Duration of the RT phase (months)					
N	52	18	14	21	
Mean (SD)	4.89 (1.455)	4.62 (1.916)	4.86 (1.289)	5.13 (1.116)	
Median	5.55	5.55	5.52	5.55	
Q1, Q3	4.99, 5.70	5.32, 5.68	4.24, 5.55	5.49, 5.55	
Min, Max	0.92, 5.78	0.43, 5.78	1.58, 5.78	1.77, 5.75	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell.

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Table 2.2410: Analysis of Rate of RBC Transfusion by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
RBC transfusion Rate in RT phase (units/month)					
N	28	24	38	15	
Mean (SD)	1.5 (1.99)	1.9 (1.77)	2.6 (2.12)	2.2 (2.31)	
Median	0.9	1.3	2.3	1.8	
Q1, Q3	0.3, 1.9	0.8, 2.9	0.5, 4.0	0.4, 2.5	
Min, Max	0.0, 8.2	0.0, 7.2	0.0, 6.6	0.0, 7.6	
Negative Binomial Model					
Adjusted for Strata					
Rate of RBC transfusion with 95% CI (units/month)	1.18 (0.76, 1.83)	1.45 (0.93, 2.27)	1.87 (1.21, 2.87)	1.52 (0.82, 2.81)	
Ratio of Rate for RBC Transfusion with 95% CI	0.81 (0.46, 1.45)	-	1.23 (0.59, 2.54)	-	
p-value	0.48	-	0.58	-	
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [1]	-	-	-	-	0.31
Unadjusted for Strata					
Rate of RBC transfusion with 95% CI (units/month)	1.43 (0.94, 2.15)	1.88 (1.21, 2.91)	2.56 (1.76, 3.71)	2.02 (1.09, 3.74)	
Ratio of Rate for RBC Transfusion with 95% CI	0.76 (0.42, 1.38)	-	1.27 (0.62, 2.61)	-	
p-value	0.37	-	0.52	-	
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [1]	-	-	-	-	0.29

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-sg-rbc-rt-csr.sas V.03.05 Output file: t-rbc-rt-csr-spv.pdf 24AUG2023:17:05

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Table 2.2410: Analysis of Rate of RBC Transfusion by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Proportional Means Model - Supportive Analysis					
Stratified					
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.71 (0.43, 1.18)	-	1.24 (0.75, 2.06)	-	
p-value	0.19	-	0.39	-	
Unstratified					
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.72 (0.40, 1.27)	-	1.48 (0.86, 2.53)	-	
p-value	0.25	-	0.16	-	
Total number of RBC transfusion unit in RT phase					
N	28	24	38	15	
Mean (SD)	6.9 (8.43)	9.5 (9.08)	11.5 (11.08)	7.5 (7.08)	
Median	5.0	7.5	10.0	5.0	
Q1, Q3	1.5, 10.0	4.5, 13.0	1.0, 17.0	2.0, 13.0	
Min, Max	0.0, 38.0	0.0, 40.0	0.0, 38.0	0.0, 25.0	
Duration of the RT phase (months)					
N	28	24	38	15	
Mean (SD)	5.28 (0.892)	5.20 (1.306)	4.59 (1.646)	4.41 (1.789)	
Median	5.55	5.55	5.54	5.55	
Q1, Q3	5.45, 5.68	5.49, 5.65	3.71, 5.62	2.46, 5.55	
Min, Max	1.58, 5.78	0.43, 5.78	0.92, 5.78	0.66, 5.75	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell.

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Table 2.2409: Analysis of Rate of RBC Transfusion by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
RBC transfusion Rate in RT phase (units/month)					
N	42	20	24	19	
Mean (SD)	1.9 (2.03)	1.5 (1.47)	2.4 (2.27)	2.4 (2.34)	
Median	1.0	1.1	2.0	1.8	
Q1, Q3	0.3, 3.1	0.4, 2.7	0.5, 3.5	0.7, 3.2	
Min, Max	0.0, 6.8	0.0, 5.0	0.0, 8.2	0.0, 7.6	
Negative Binomial Model					
Adjusted for Strata					
Rate of RBC transfusion with 95% CI (units/month)	1.33 (0.86, 2.05)	1.12 (0.65, 1.95)	1.87 (1.23, 2.85)	1.85 (1.15, 2.97)	
Ratio of Rate for RBC Transfusion with 95% CI	1.18 (0.64, 2.18)	-	1.01 (0.55, 1.86)	-	
p-value	0.60	-	0.98	-	
Adjusted interaction test for Treatment*Baseline TSS Group [1]	-	-	-	-	0.73
Unadjusted for Strata					
Rate of RBC transfusion with 95% CI (units/month)	1.90 (1.33, 2.73)	1.55 (0.91, 2.63)	2.39 (1.53, 3.71)	2.34 (1.42, 3.85)	
Ratio of Rate for RBC Transfusion with 95% CI	1.23 (0.65, 2.32)	-	1.02 (0.52, 1.99)	-	
p-value	0.53	-	0.95	-	
Unadjusted interaction test for Treatment*Baseline TSS Group [1]	-	-	-	-	0.70

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-sg-rbc-rt-csr.sas V.03.05 Output file: t-rbc-rt-csr-tss.pdf 24AUG2023:17:05

Table 2.2409: Analysis of Rate of RBC Transfusion by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Proportional Means Model - Supportive Analysis					
Stratified					
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	1.05 (0.66, 1.67)	-	0.94 (0.56, 1.57)	-	
p-value	0.83	-	0.81	-	
Unstratified					
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	1.22 (0.73, 2.02)	-	1.04 (0.60, 1.80)	-	
p-value	0.45	-	0.90	-	
Total number of RBC transfusion unit in RT phase					
N	42	20	24	19	
Mean (SD)	9.4 (10.92)	7.7 (6.99)	9.9 (9.08)	9.9 (9.60)	
Median	5.5	6.0	8.5	8.0	
Q1, Q3	1.0, 13.0	2.5, 11.5	2.0, 14.5	4.0, 13.0	
Min, Max	0.0, 38.0	0.0, 25.0	0.0, 32.0	0.0, 40.0	
Duration of the RT phase (months)					
N	42	20	24	19	
Mean (SD)	5.05 (1.253)	5.03 (1.477)	4.59 (1.641)	4.75 (1.627)	
Median	5.55	5.55	5.52	5.55	
Q1, Q3	5.45, 5.72	5.49, 5.70	3.91, 5.57	5.32, 5.55	
Min, Max	0.95, 5.78	0.43, 5.78	0.92, 5.78	0.66, 5.78	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
[1] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding Negative Binomial regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
RBC = Red Blood Cell.

Table 2.2401: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
All Strata Combined			
RBC transfusion Rate in RT phase (units/month)			
N	66	39	105
Mean (SD)	2.1 (2.12)	2.0 (1.97)	2.1 (2.06)
Median	1.6	1.4	1.4
Q1, Q3	0.3, 3.3	0.5, 2.9	0.4, 3.0
Min, Max	0.0, 8.2	0.0, 7.6	0.0, 8.2
Negative Binomial Model			
Adjusted for Strata			
Rate of RBC transfusion with 95% CI (units/month)	1.58 (1.16, 2.15)	1.44 (1.00, 2.08)	
Ratio of Rate for RBC Transfusion with 95% CI	1.10 (0.71, 1.70)	-	-
p-value	0.68	-	-
Unadjusted for Strata			
Rate of RBC transfusion with 95% CI (units/month)	2.08 (1.57, 2.75)	1.93 (1.33, 2.79)	
Ratio of Rate for RBC Transfusion with 95% CI	1.08 (0.68, 1.71)	-	-
p-value	0.76	-	-
Proportional Means Model - Supportive Analysis			
Stratified			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	1.00 (0.71, 1.40)	-	-
p-value	0.98	-	-
Unstratified			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	1.09 (0.74, 1.61)	-	-
p-value	0.65	-	-

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

Table 2.2401: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Total number of RBC transfusion unit in RT phase			
N	66	39	105
Mean (SD)	9.6 (10.22)	8.7 (8.33)	9.3 (9.53)
Median	6.0	7.0	6.0
Q1, Q3	1.0, 13.0	3.0, 13.0	2.0, 13.0
Min, Max	0.0, 38.0	0.0, 40.0	0.0, 40.0
Duration of the RT phase (months)			
N	66	39	105
Mean (SD)	4.88 (1.412)	4.90 (1.538)	4.89 (1.452)
Median	5.55	5.55	5.55
Q1, Q3	4.70, 5.65	5.42, 5.62	5.32, 5.65
Min, Max	0.92, 5.78	0.43, 5.78	0.43, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell

Table 2.2401: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Stratum 1			
Transfusion Dependence at Baseline = 'Yes' and TSS < 18 at Baseline			
RBC transfusion Rate in RT phase (units/month)			
N	35	14	49
Mean (SD)	2.1 (2.14)	2.0 (1.50)	2.0 (1.96)
Median	1.0	1.3	1.3
Q1, Q3	0.4, 3.3	0.9, 3.0	0.5, 3.1
Min, Max	0.0, 6.8	0.0, 5.0	0.0, 6.8
Negative Binomial Model			
Rate of RBC transfusion with 95% CI (units/month)	2.05 (1.44, 2.91)	2.03 (1.15, 3.57)	
Ratio of Rate for RBC Transfusion with 95% CI	1.01 (0.52, 1.97)	-	-
Proportional Means Model - Supportive Analysis			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	1.02 (0.63, 1.66)	-	-
Total number of RBC transfusion in stratum 1 in RT phase			
N	35	14	49
Mean (SD)	10.6 (11.47)	9.8 (7.06)	10.4 (10.33)
Median	6.0	7.5	7.0
Q1, Q3	2.0, 16.0	5.0, 16.0	2.0, 16.0
Min, Max	0.0, 38.0	0.0, 25.0	0.0, 38.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

Table 2.2401: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Duration of the RT phase (months) in stratum 1			
N	35	14	49
Mean (SD)	5.27 (0.854)	4.96 (1.690)	5.18 (1.145)
Median	5.55	5.55	5.55
Q1, Q3	5.49, 5.72	5.49, 5.75	5.49, 5.72
Min, Max	2.14, 5.78	0.43, 5.78	0.43, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell

Table 2.2401: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Stratum 2			
Transfusion Dependence at Baseline = 'Yes' and TSS >= 18 at Baseline			
RBC transfusion Rate in RT phase (units/month)			
N	17	11	28
Mean (SD)	2.9 (2.47)	3.5 (2.45)	3.1 (2.44)
Median	2.2	2.5	2.4
Q1, Q3	0.7, 4.5	1.4, 6.2	1.3, 5.2
Min, Max	0.0, 8.2	1.0, 7.6	0.0, 8.2
Negative Binomial Model			
Rate of RBC transfusion with 95% CI (units/month)	2.79 (1.80, 4.32)	3.37 (1.96, 5.80)	
Ratio of Rate for RBC Transfusion with 95% CI	0.83 (0.41, 1.66)	-	-
Proportional Means Model - Supportive Analysis			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.81 (0.45, 1.45)	-	-
Total number of RBC transfusion in stratum 2 in RT phase			
N	17	11	28
Mean (SD)	11.2 (9.78)	14.0 (10.25)	12.3 (9.88)
Median	9.0	10.0	10.0
Q1, Q3	4.0, 16.0	8.0, 18.0	5.5, 16.5
Min, Max	0.0, 32.0	5.0, 40.0	0.0, 40.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

Table 2.2401: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Duration of the RT phase (months) in stratum 2			
N	17	11	28
Mean (SD)	4.64 (1.641)	4.75 (1.768)	4.68 (1.660)
Median	5.52	5.55	5.54
Q1, Q3	4.67, 5.55	5.32, 5.55	4.98, 5.55
Min, Max	0.92, 5.78	0.66, 5.78	0.66, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell

Table 2.2401: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Stratum 3			
Transfusion Dependence at Baseline = 'No' and TSS < 18 at Baseline			
RBC transfusion Rate in RT phase (units/month)			
N	7	6	13
Mean (SD)	1.2 (1.23)	0.5 (0.66)	0.9 (1.04)
Median	1.0	0.2	0.4
Q1, Q3	0.0, 2.1	0.0, 0.9	0.0, 1.6
Min, Max	0.0, 3.1	0.0, 1.6	0.0, 3.1
Negative Binomial Model			
Rate of RBC transfusion with 95% CI (units/month)	1.12 (0.35, 3.58)	0.49 (0.14, 1.66)	
Ratio of Rate for RBC Transfusion with 95% CI	2.29 (0.42, 12.44)	-	-
Proportional Means Model - Supportive Analysis			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	1.46 (0.39, 5.49)	-	-
Total number of RBC transfusion in stratum 3 in RT phase			
N	7	6	13
Mean (SD)	3.0 (3.70)	2.7 (3.67)	2.8 (3.53)
Median	2.0	1.0	2.0
Q1, Q3	0.0, 6.0	0.0, 5.0	0.0, 5.0
Min, Max	0.0, 10.0	0.0, 9.0	0.0, 10.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

Table 2.2401: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Duration of the RT phase (months) in stratum 3			
N	7	6	13
Mean (SD)	3.96 (2.220)	5.21 (0.899)	4.54 (1.796)
Median	5.49	5.55	5.55
Q1, Q3	1.02, 5.72	5.49, 5.59	3.38, 5.59
Min, Max	0.95, 5.78	3.38, 5.72	0.95, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell

Table 2.2401: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Stratum 4			
Transfusion Dependence at Baseline = 'No' and TSS >= 18 at Baseline			
RBC transfusion Rate in RT phase (units/month)			
N	7	8	15
Mean (SD)	1.3 (1.20)	0.9 (1.05)	1.1 (1.10)
Median	1.9	0.5	0.7
Q1, Q3	0.0, 2.2	0.0, 2.1	0.0, 2.2
Min, Max	0.0, 2.9	0.0, 2.4	0.0, 2.9
Negative Binomial Model			
Rate of RBC transfusion with 95% CI (units/month)	1.37 (0.54, 3.47)	0.93 (0.38, 2.29)	
Ratio of Rate for RBC Transfusion with 95% CI	1.47 (0.40, 5.36)	-	-
Proportional Means Model - Supportive Analysis			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	1.73 (0.69, 4.31)	-	-
Total number of RBC transfusion in stratum 4 in RT phase			
N	7	8	15
Mean (SD)	6.9 (6.77)	4.3 (4.92)	5.5 (5.79)
Median	7.0	3.0	4.0
Q1, Q3	0.0, 12.0	0.0, 7.5	0.0, 11.0
Min, Max	0.0, 17.0	0.0, 13.0	0.0, 17.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

Table 2.2401: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	Total (N=105)
Duration of the RT phase (months) in stratum 4			
N	7	8	15
Mean (SD)	4.48 (1.768)	4.76 (1.529)	4.63 (1.590)
Median	5.49	5.55	5.55
Q1, Q3	3.68, 5.78	4.01, 5.59	3.68, 5.62
Min, Max	0.95, 5.78	2.10, 5.65	0.95, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell

Data Extracted: CRF data: 25JUN2019

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Table 2.5602: Analysis of Time to First Unit of Any Type Transfused by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Subjects with Event					
First Unit of Any Type Transfused, n(%)	19 (79.2%)	7 (77.8%)	35 (83.3%)	26 (86.7%)	
Censor					
Subjects Censored, n(%)	5 (20.8%)	2 (22.2%)	7 (16.7%)	4 (13.3%)	
Kaplan-Meier Estimate of Time to First Unit of Any Type Transfused (Weeks)					
25-percentile (95% CI)	0.86 (0.29, 1.86)	2.00 (0.43, 4.29)	0.57 (0.29, 1.29)	0.86 (0.29, 1.43)	
Median (95% CI)	3.14 (0.86, 6.14)	4.29 (0.43, NE)	2.00 (1.14, 2.43)	2.00 (1.43, 4.00)	
75-percentile (95% CI)	9.57 (4.14, NE)	6.57 (2.57, NE)	5.86 (2.29, NE)	4.86 (2.14, 12.00)	
Min, Max	0.29, 24.86	0.43, 24.86	0.29, 25.14	0.29, 24.29	
Stratified Log-Rank Test p-value	0.84		0.24		
Adjusted Hazard Ratio (95% CI)	1.22 (0.48, 3.12)		0.68 (0.39, 1.18)		
Unstratified Log-Rank Test p-value	0.85		0.93		
Unadjusted Hazard Ratio (95% CI)	1.09 (0.46, 2.60)		0.98 (0.59, 1.63)		
P-value for interaction test					0.49

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-any-tran-sub.sas V.03.05 Output file: t-tte-any-tran-age.pdf 24AUG2023:16:42

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Table 2.5606: Analysis of Time to First Unit of Any Type Transfused by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Subjects with Event					
First Unit of Any Type Transfused, n(%)	42 (85.7%)	26 (83.9%)	12 (70.6%)	7 (87.5%)	
Censor					
Subjects Censored, n(%)	7 (14.3%)	5 (16.1%)	5 (29.4%)	1 (12.5%)	
Kaplan-Meier Estimate of Time to First Unit of Any Type Transfused (Weeks)					
25-percentile (95% CI)	0.57 (0.29, 1.29)	1.29 (0.43, 2.00)	1.00 (0.43, 2.00)	0.57 (0.29, 1.43)	
Median (95% CI)	2.00 (1.14, 2.71)	2.71 (1.71, 4.57)	2.00 (0.71, 6.29)	1.43 (0.29, NE)	
75-percentile (95% CI)	6.14 (2.71, NE)	6.14 (4.00, NE)	NE (2.00, NE)	5.86 (0.86, NE)	
Min, Max	0.29, 25.14	0.29, 24.86	0.43, 24.86	0.29, 9.86	
Stratified Log-Rank Test p-value	0.55		0.21		
Adjusted Hazard Ratio (95% CI)	0.85 (0.50, 1.45)		0.48 (0.16, 1.44)		
Unstratified Log-Rank Test p-value	0.57		0.18		
Unadjusted Hazard Ratio (95% CI)	1.15 (0.71, 1.89)		0.52 (0.20, 1.36)		
P-value for interaction test					0.16

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-any-tran-sub.sas V.03.05 Output file: t-tte-any-tran-dipss2.pdf 24AUG2023:16:42

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Table 2.5605: Analysis of Time to First Unit of Any Type Transfused by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Subjects with Event				
First Unit of Any Type Transfused, n(%)	3 (60.0%)	7 (100.0%)	39 (88.6%)	19 (79.2%)
Censor				
Subjects Censored, n(%)	2 (40.0%)	0	5 (11.4%)	5 (20.8%)
Kaplan-Meier Estimate of Time to First Unit of Any Type Transfused (Weeks)				
25-percentile (95% CI)	4.14 (2.00, NE)	0.43 (0.29, 2.57)	0.57 (0.29, 1.00)	1.36 (0.43, 2.00)
Median (95% CI)	9.00 (2.00, NE)	2.57 (0.29, 4.29)	1.86 (0.86, 2.71)	2.71 (1.43, 6.14)
75-percentile (95% CI)	NE (2.00, NE)	4.29 (2.00, NE)	5.93 (2.14, NE)	9.29 (4.57, NE)
Min, Max	2.00, 23.86	0.29, 4.57	0.29, 25.14	0.43, 24.86
Stratified Log-Rank Test p-value	0.53		0.89	
Adjusted Hazard Ratio (95% CI)	0.52 (0.08, 3.20)		1.01 (0.53, 1.91)	
Unstratified Log-Rank Test p-value	0.040		0.17	
Unadjusted Hazard Ratio (95% CI)	0.22 (0.04, 1.08)		1.46 (0.84, 2.54)	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.5605: Analysis of Time to First Unit of Any Type Transfused by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=17)	High Risk BAT (N=8)	p-value
Subjects with Event			
First Unit of Any Type Transfused, n(%)	12 (70.6%)	7 (87.5%)	
Censor			
Subjects Censored, n(%)	5 (29.4%)	1 (12.5%)	
Kaplan-Meier Estimate of Time to First Unit of Any Type Transfused (Weeks)			
25-percentile (95% CI)	1.00 (0.43, 2.00)	0.57 (0.29, 1.43)	
Median (95% CI)	2.00 (0.71, 6.29)	1.43 (0.29, NE)	
75-percentile (95% CI)	NE (2.00, NE)	5.86 (0.86, NE)	
Min, Max	0.43, 24.86	0.29, 9.86	
Stratified Log-Rank Test p-value	0.21		
Adjusted Hazard Ratio (95% CI)	0.48 (0.16, 1.44)		
Unstratified Log-Rank Test p-value	0.18		
Unadjusted Hazard Ratio (95% CI)	0.52 (0.20, 1.36)		
P-value for interaction test			0.22

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-any-tran-sub.sas V.03.05 Output file: t-tte-any-tran-dipss3.pdf 24AUG2023:16:42

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Table 2.5604: Analysis of Time to First Unit of Any Type Transfused by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Subjects with Event					
First Unit of Any Type Transfused, n(%)	21 (72.4%)	4 (57.1%)	33 (89.2%)	29 (90.6%)	
Censor					
Subjects Censored, n(%)	8 (27.6%)	3 (42.9%)	4 (10.8%)	3 (9.4%)	
Kaplan-Meier Estimate of Time to First Unit of Any Type Transfused (Weeks)					
25-percentile (95% CI)	0.86 (0.29, 1.43)	1.43 (0.29, 4.29)	0.57 (0.29, 1.43)	0.86 (0.43, 1.71)	
Median (95% CI)	2.14 (1.00, 6.29)	4.29 (0.29, NE)	2.00 (1.00, 2.71)	2.00 (1.29, 4.57)	
75-percentile (95% CI)	NE (4.14, NE)	NE (2.57, NE)	5.86 (2.14, NE)	5.50 (2.71, 12.00)	
Min, Max	0.29, 24.14	0.29, 24.14	0.29, 25.14	0.29, 24.86	
Stratified Log-Rank Test p-value	0.88		0.62		
Adjusted Hazard Ratio (95% CI)	0.96 (0.32, 2.91)		0.83 (0.48, 1.42)		
Unstratified Log-Rank Test p-value	0.57		0.95		
Unadjusted Hazard Ratio (95% CI)	1.36 (0.47, 3.98)		1.01 (0.61, 1.68)		
P-value for interaction test					0.65

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-any-tran-sub.sas V.03.05 Output file: t-tte-any-tran-geo.pdf 24AUG2023:16:42

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Table 2.5607: Analysis of Time to First Unit of Any Type Transfused by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Subjects with Event					
First Unit of Any Type Transfused, n(%)	26 (96.3%)	6 (100.0%)	28 (71.8%)	27 (81.8%)	
Censor					
Subjects Censored, n(%)	1 (3.7%)	0	11 (28.2%)	6 (18.2%)	
Kaplan-Meier Estimate of Time to First Unit of Any Type Transfused (Weeks)					
25-percentile (95% CI)	0.57 (0.29, 1.14)	0.43 (0.29, 1.43)	0.86 (0.29, 1.86)	1.43 (0.43, 2.00)	
Median (95% CI)	1.43 (0.71, 2.14)	1.36 (0.29, NE)	4.14 (1.43, 7.14)	2.71 (1.71, 4.86)	
75-percentile (95% CI)	2.71 (1.86, 6.29)	2.00 (0.43, NE)	25.14 (6.00, NE)	6.57 (4.00, NE)	
Min, Max	0.29, 23.57	0.29, 4.29	0.29, 25.14	0.29, 24.86	
Stratified Log-Rank Test p-value	0.31		0.20		
Adjusted Hazard Ratio (95% CI)	0.72 (0.29, 1.82)		0.66 (0.37, 1.18)		
Unstratified Log-Rank Test p-value	0.52		0.38		
Unadjusted Hazard Ratio (95% CI)	0.74 (0.30, 1.82)		0.79 (0.46, 1.35)		
P-value for interaction test					0.92

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-any-tran-sub.sas V.03.05 Output file: t-tte-any-tran-hgb.pdf 24AUG2023:16:43

Table 2.5608: Analysis of Time to First Unit of Any Type Transfused by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=13)	BAT (N=8)	MMB (N=8)	BAT (N=8)
Subjects with Event				
First Unit of Any Type Transfused, n(%)	11 (84.6%)	5 (62.5%)	7 (87.5%)	7 (87.5%)
Censor				
Subjects Censored, n(%)	2 (15.4%)	3 (37.5%)	1 (12.5%)	1 (12.5%)
Kaplan-Meier Estimate of Time to First Unit of Any Type Transfused (Weeks)				
25-percentile (95% CI)	0.43 (0.29, 0.57)	2.21 (1.43, 6.57)	1.79 (0.29, 2.43)	1.64 (0.71, 4.57)
Median (95% CI)	0.57 (0.29, 2.14)	2.71 (1.43, NE)	2.29 (0.29, 10.14)	3.36 (0.71, 9.86)
75-percentile (95% CI)	2.14 (0.57, NE)	NE (2.71, NE)	6.43 (2.14, NE)	8.00 (2.00, NE)
Min, Max	0.29, 24.29	1.43, 24.14	0.29, 24.14	0.71, 24.86
Stratified Log-Rank Test p-value	0.14		0.44	
Adjusted Hazard Ratio (95% CI)	2.37 (0.68, 8.29)		0.44 (0.11, 1.75)	
Unstratified Log-Rank Test p-value	0.097		0.99	
Unadjusted Hazard Ratio (95% CI)	2.40 (0.83, 6.97)		1.02 (0.35, 2.94)	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-any-tran-sub.sas V.03.05 Output file: t-tte-any-tran-mf.pdf 24AUG2023:16:43

Table 2.5608: Analysis of Time to First Unit of Any Type Transfused by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Primary Myelofibrosis MMB (N=45)	Primary Myelofibrosis BAT (N=23)	p-value
Subjects with Event			
First Unit of Any Type Transfused, n(%)	36 (80.0%)	21 (91.3%)	
Censor			
Subjects Censored, n(%)	9 (20.0%)	2 (8.7%)	
Kaplan-Meier Estimate of Time to First Unit of Any Type Transfused (Weeks)			
25-percentile (95% CI)	1.00 (0.43, 1.43)	0.71 (0.29, 1.43)	
Median (95% CI)	2.00 (1.29, 5.86)	1.86 (0.86, 4.00)	
75-percentile (95% CI)	7.14 (4.14, NE)	4.57 (2.00, 12.00)	
Min, Max	0.29, 25.14	0.29, 24.29	
Stratified Log-Rank Test p-value	0.12		
Adjusted Hazard Ratio (95% CI)	0.61 (0.35, 1.07)		
Unstratified Log-Rank Test p-value	0.19		
Unadjusted Hazard Ratio (95% CI)	0.69 (0.40, 1.20)		
P-value for interaction test			0.11

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-any-tran-sub.sas V.03.05 Output file: t-tte-any-tran-mf.pdf 24AUG2023:16:43

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Table 2.5603: Analysis of Time to First Unit of Any Type Transfused by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Subjects with Event					
First Unit of Any Type Transfused, n(%)	42 (80.8%)	16 (88.9%)	12 (85.7%)	17 (81.0%)	
Censor					
Subjects Censored, n(%)	10 (19.2%)	2 (11.1%)	2 (14.3%)	4 (19.0%)	
Kaplan-Meier Estimate of Time to First Unit of Any Type Transfused (Weeks)					
25-percentile (95% CI)	0.79 (0.43, 1.43)	1.43 (0.29, 1.86)	0.57 (0.29, 1.29)	0.86 (0.29, 2.00)	
Median (95% CI)	2.00 (1.43, 4.14)	2.00 (1.43, 4.57)	1.71 (0.29, 5.86)	2.57 (0.86, 6.14)	
75-percentile (95% CI)	7.14 (4.14, NE)	4.57 (2.00, 12.00)	5.86 (1.29, NE)	6.57 (2.71, NE)	
Min, Max	0.29, 25.14	0.29, 24.29	0.29, 24.00	0.29, 24.86	
Stratified Log-Rank Test p-value	0.35		0.31		
Adjusted Hazard Ratio (95% CI)	0.72 (0.40, 1.31)		0.64 (0.27, 1.53)		
Unstratified Log-Rank Test p-value	0.46		0.41		
Unadjusted Hazard Ratio (95% CI)	0.80 (0.45, 1.42)		1.38 (0.66, 2.89)		
P-value for interaction test					0.73

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-any-tran-sub.sas V.03.05 Output file: t-tte-any-tran-sex.pdf 24AUG2023:16:42

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Table 2.5610: Analysis of Time to First Unit of Any Type Transfused by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Subjects with Event					
First Unit of Any Type Transfused, n(%)	23 (82.1%)	20 (83.3%)	31 (81.6%)	13 (86.7%)	
Censor					
Subjects Censored, n(%)	5 (17.9%)	4 (16.7%)	7 (18.4%)	2 (13.3%)	
Kaplan-Meier Estimate of Time to First Unit of Any Type Transfused (Weeks)					
25-percentile (95% CI)	0.50 (0.29, 1.29)	1.14 (0.29, 2.00)	1.00 (0.43, 1.43)	0.86 (0.43, 1.71)	
Median (95% CI)	2.07 (0.57, 2.71)	2.57 (1.43, 4.86)	2.00 (1.14, 5.86)	1.86 (0.71, 4.57)	
75-percentile (95% CI)	6.00 (2.14, NE)	6.14 (2.71, NE)	9.00 (4.14, NE)	6.14 (1.86, NE)	
Min, Max	0.29, 24.29	0.29, 24.86	0.29, 25.14	0.43, 24.14	
Stratified Log-Rank Test p-value	0.63		0.25		
Adjusted Hazard Ratio (95% CI)	0.87 (0.46, 1.63)		0.61 (0.30, 1.26)		
Unstratified Log-Rank Test p-value	0.72		0.64		
Unadjusted Hazard Ratio (95% CI)	1.12 (0.62, 2.04)		0.86 (0.45, 1.64)		
P-value for interaction test					0.48

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-any-tran-sub.sas V.03.05 Output file: t-tte-any-tran-svb.pdf 24AUG2023:16:43

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Table 2.5609: Analysis of Time to First Unit of Any Type Transfused by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Subjects with Event					
First Unit of Any Type Transfused, n(%)	34 (81.0%)	17 (85.0%)	20 (83.3%)	16 (84.2%)	
Censor					
Subjects Censored, n(%)	8 (19.0%)	3 (15.0%)	4 (16.7%)	3 (15.8%)	
Kaplan-Meier Estimate of Time to First Unit of Any Type Transfused (Weeks)					
25-percentile (95% CI)	0.71 (0.29, 1.29)	1.57 (0.71, 2.00)	0.57 (0.29, 1.43)	0.43 (0.29, 1.43)	
Median (95% CI)	2.14 (1.14, 4.14)	2.00 (1.43, 4.29)	1.93 (0.57, 2.71)	2.57 (0.43, 6.14)	
75-percentile (95% CI)	7.14 (4.14, NE)	4.57 (2.14, NE)	6.00 (2.00, NE)	6.57 (2.57, NE)	
Min, Max	0.29, 24.86	0.71, 24.86	0.29, 25.14	0.29, 24.14	
Stratified Log-Rank Test p-value	0.37		0.59		
Adjusted Hazard Ratio (95% CI)	0.74 (0.40, 1.37)		0.78 (0.38, 1.59)		
Unstratified Log-Rank Test p-value	0.79		0.94		
Unadjusted Hazard Ratio (95% CI)	0.92 (0.51, 1.66)		1.03 (0.53, 2.02)		
P-value for interaction test					0.97

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment and baseline TD (yes,no).
Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-any-tran-sub.sas V.03.05 Output file: t-tte-any-tran-tss.pdf 24AUG2023:16:43

Table 2.5601: Analysis of Time to First Unit of Any Type Transfused
Randomized Treatment Phase
ITT-Anemic Analysis Set

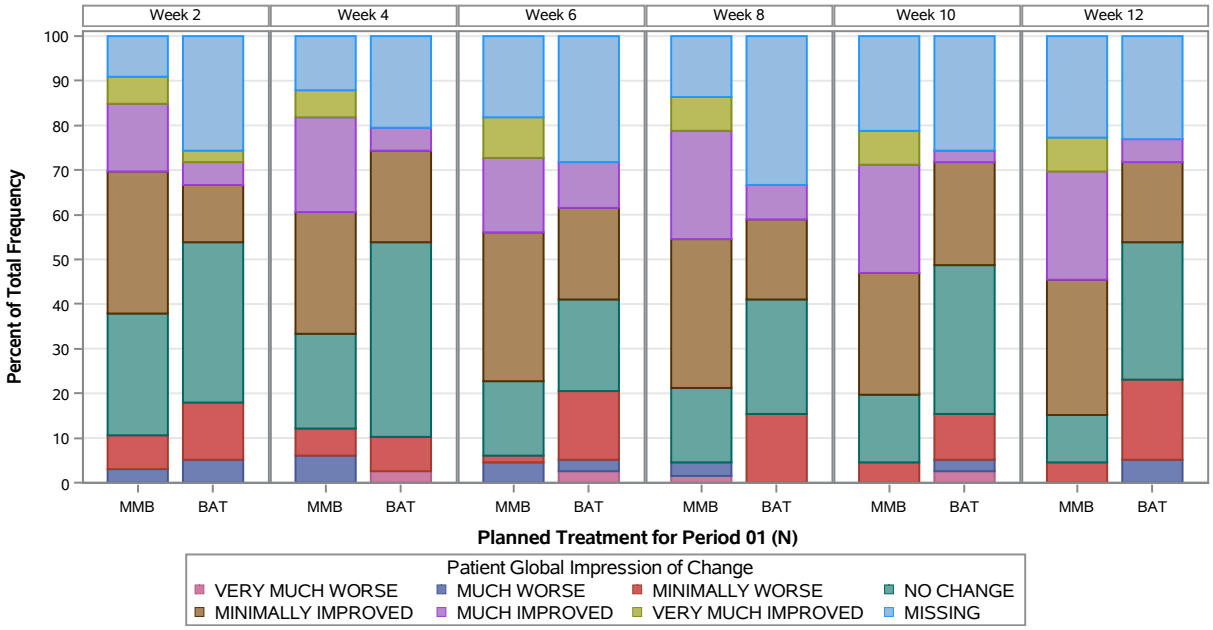
	MMB (N=66)	BAT (N=39)
Subjects with Event		
First Unit of Any Type Transfused, n(%)	**54 (81.8%)**	**33 (84.6%)**
Censor		
Subjects Censored, n(%)	**12 (18.2%)**	**6 (15.4%)**
Kaplan-Meier Estimate of Time to First Unit of Any Type Transfused (Weeks)		
25-percentile (95% CI)	**0.71 (0.43, 1.14)**	**0.86 (0.43, 1.71)**
Median (95% CI)	**2.00 (1.29, 2.71)**	**2.14 (1.43, 4.29)**
75-percentile (95% CI)	**6.29 (3.43, NE)**	**6.14 (2.71, NE)**
Min, Max	**0.29, 25.14**	**0.29, 24.86**
Stratified Log-Rank Test p-value	**0.31**	
Adjusted Hazard Ratio (95% CI)	**0.77 (0.48, 1.22)**	
Unstratified Log-Rank Test p-value	**0.91**	
Unadjusted Hazard Ratio (95% CI)	**0.97 (0.63, 1.51)**	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

2.7 PGIC

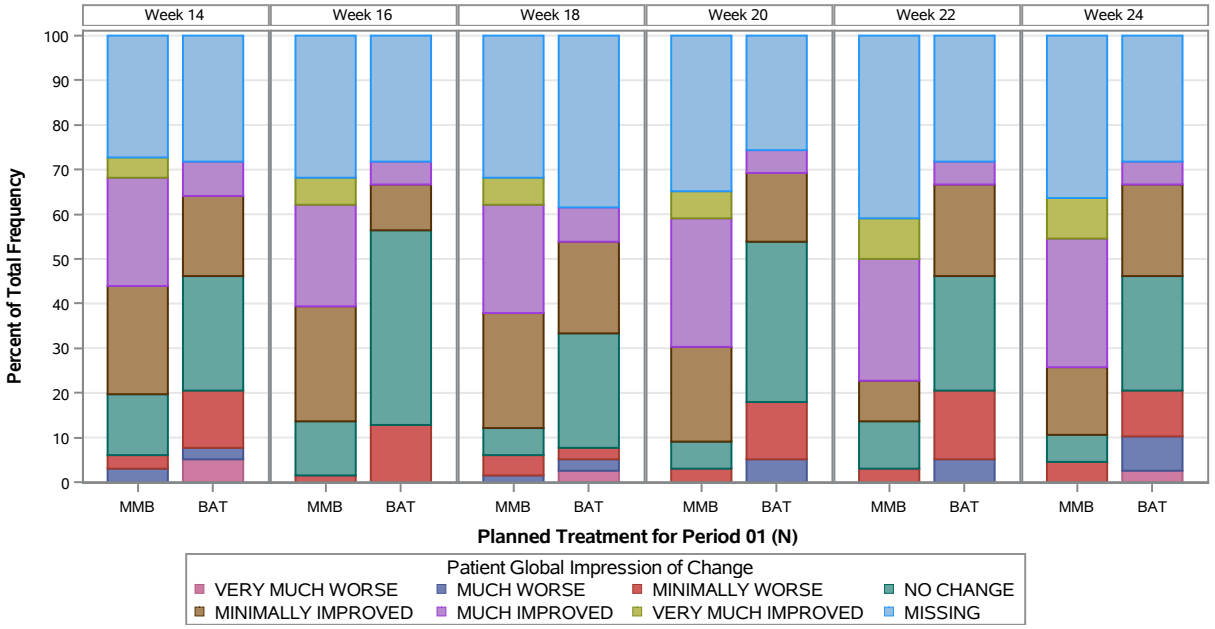
Figure 2.3501: Stacked Bar Chart of Patient Global Impression of Change over time
Randomized Treatment Phase
ITT-Anemic Analysis Set



ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-pgic-bar.sas V.03.05
Output file: g-pgic-bar.pdf 14JUL2023:10:45

Figure 2.3501: Stacked Bar Chart of Patient Global Impression of Change over time
Randomized Treatment Phase
ITT-Anemic Analysis Set



ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-pgic-bar.sas V.03.05
Output file: g-pgic-bar.pdf 14JUL2023:10:45

Table 2.7901: Analysis of Patient Global Impression of Change
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	ET Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 43)	Switch (BAT->MMB) (N = 30)	Total (N = 73)	MMB in RT (N = 66)	Total (N = 96)
Best PGIC Assessment at Any Timepoint of Overall Exposed to MMB, n (%)					
Improvement, n(%)				57 (86.4%)	73 (76.0%)
Very much improved				12 (18.2%)	12 (12.5%)
Much improved				27 (40.9%)	39 (40.6%)
Minimally improved				18 (27.3%)	22 (22.9%)
95% Exact CI				0.7569, 0.9357	0.6625, 0.8417
Worsening, n(%)				5 (7.6%)	7 (7.3%)
Minimally worse				3 (4.5%)	4 (4.2%)
Much worse				2 (3.0%)	3 (3.1%)
Very much worse				0	0
95% Exact CI				0.0251, 0.1680	0.0298, 0.1445
Missing Assessment				1 (1.5%)	11 (11.5%)
No change				3 (4.5%)	5 (5.2%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-pgic-ext.sas V.03.05 Output file: t-chg-pgic-ext.pdf 24AUG2023:16:54

Table 2.7901: Analysis of Patient Global Impression of Change
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	ET Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 43)	Switch (BAT->MMB) (N = 30)	Total (N = 73)	MMB in RT (N = 66)	Total (N = 96)
Best PGIC Assessment at Any Timepoint in ET Phase, n (%)					
Subjects Ongoing and not Reach the 1st Assessment Timepoint in ET Phase	0	0	0		
Subjects discontinued or Reached the 1st Assessment Timepoint in ET Phase	43	30	73		
Improvement, n(%)	31 (72.1%)	16 (53.3%)	47 (64.4%)		
Very much improved	7 (16.3%)	0	7 (9.6%)		
Much improved	15 (34.9%)	12 (40.0%)	27 (37.0%)		
Minimally improved	9 (20.9%)	4 (13.3%)	13 (17.8%)		
95% Exact CI	0.5633, 0.8467	0.3433, 0.7166	0.5231, 0.7525		
Worsening, n(%)	5 (11.6%)	2 (6.7%)	7 (9.6%)		
Minimally worse	2 (4.7%)	1 (3.3%)	3 (4.1%)		
Much worse	3 (7.0%)	1 (3.3%)	4 (5.5%)		
Very much worse	0	0	0		
95% Exact CI	0.0389, 0.2508	0.0082, 0.2207	0.0394, 0.1876		
Missing Assessment	5 (11.6%)	10 (33.3%)	15 (20.5%)		
No change	2 (4.7%)	2 (6.7%)	4 (5.5%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-pgic-ext.sas V.03.05 Output file: t-chg-pgic-ext.pdf 24AUG2023:16:54

Table 2.7901: Analysis of Patient Global Impression of Change
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	ET Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 43)	Switch (BAT->MMB) (N = 30)	Total (N = 73)	MMB in RT (N = 66)	Total (N = 96)
Week 24 in Extended Treatment Phase, n(%)					
Subjects Ongoing and not Reach Week 24 in ET Phase	0	0	0		
Subjects Evaluable for Analysis of PGIC at Week 24 in ET Phase	43	30	73		
Improvement, n(%)	22 (51.2%)	11 (36.7%)	33 (45.2%)		
Very much improved	2 (4.7%)	0	2 (2.7%)		
Much improved	13 (30.2%)	5 (16.7%)	18 (24.7%)		
Minimally improved	7 (16.3%)	6 (20.0%)	13 (17.8%)		
95% Exact CI	0.3546, 0.6669	0.1993, 0.5614	0.3352, 0.5730		
Worsening, n(%)	2 (4.7%)	1 (3.3%)	3 (4.1%)		
Minimally worse	1 (2.3%)	1 (3.3%)	2 (2.7%)		
Much worse	1 (2.3%)	0	1 (1.4%)		
Very much worse	0	0	0		
95% Exact CI	0.0057, 0.1581	0.0008, 0.1722	0.0086, 0.1154		
Missing Assessment	16 (37.2%)	14 (46.7%)	30 (41.1%)		
No change	3 (7.0%)	4 (13.3%)	7 (9.6%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-pgic-ext.sas V.03.05 Output file: t-chg-pgic-ext.pdf 24AUG2023:16:54

Table 2.7901: Analysis of Patient Global Impression of Change
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	ET Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 43)	Switch (BAT->MMB) (N = 30)	Total (N = 73)	MMB in RT (N = 66)	Total (N = 96)
Week 12 in Extended Treatment Phase, n(%)					
Subjects Ongoing and not Reach Week 12 in ET Phase	0	0	0		
Subjects Evaluable for Analysis of PGIC at Week 12 in ET Phase	43	30	73		
Improvement, n(%)	26 (60.5%)	13 (43.3%)	39 (53.4%)		
Very much improved	5 (11.6%)	0	5 (6.8%)		
Much improved	12 (27.9%)	5 (16.7%)	17 (23.3%)		
Minimally improved	9 (20.9%)	8 (26.7%)	17 (23.3%)		
95% Exact CI	0.4441, 0.7502	0.2546, 0.6257	0.4137, 0.6520		
Worsening, n(%)	5 (11.6%)	2 (6.7%)	7 (9.6%)		
Minimally worse	3 (7.0%)	1 (3.3%)	4 (5.5%)		
Much worse	2 (4.7%)	1 (3.3%)	3 (4.1%)		
Very much worse	0	0	0		
95% Exact CI	0.0389, 0.2508	0.0082, 0.2207	0.0394, 0.1876		
Missing Assessment	8 (18.6%)	14 (46.7%)	22 (30.1%)		
No change	4 (9.3%)	1 (3.3%)	5 (6.8%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification

Table 2.7901: Analysis of Patient Global Impression of Change
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	ET Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 43)	Switch (BAT->MMB) (N = 30)	Total (N = 73)	MMB in RT (N = 66)	Total (N = 96)
Week 36 in Extended Treatment Phase, n(%)					
Subjects Ongoing and not Reach Week 36 in ET Phase	0	0	0		
Subjects Evaluable for Analysis of PGIC at Week 36 in ET Phase	43	30	73		
Improvement, n(%)	18 (41.9%)	9 (30.0%)	27 (37.0%)		
Very much improved	2 (4.7%)	0	2 (2.7%)		
Much improved	7 (16.3%)	4 (13.3%)	11 (15.1%)		
Minimally improved	9 (20.9%)	5 (16.7%)	14 (19.2%)		
95% Exact CI	0.2701, 0.5787	0.1473, 0.4940	0.2597, 0.4909		
Worsening, n(%)	5 (11.6%)	3 (10.0%)	8 (11.0%)		
Minimally worse	3 (7.0%)	3 (10.0%)	6 (8.2%)		
Much worse	2 (4.7%)	0	2 (2.7%)		
Very much worse	0	0	0		
95% Exact CI	0.0389, 0.2508	0.0211, 0.2653	0.0485, 0.2046		
Missing Assessment	18 (41.9%)	17 (56.7%)	35 (47.9%)		
No change	2 (4.7%)	1 (3.3%)	3 (4.1%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-pgic-ext.sas V.03.05 Output file: t-chg-pgic-ext.pdf 24AUG2023:16:54

Table 2.7901: Analysis of Patient Global Impression of Change
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	ET Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 43)	Switch (BAT->MMB) (N = 30)	Total (N = 73)	MMB in RT (N = 66)	Total (N = 96)
Week 48 in Extended Treatment Phase, n(%)					
Subjects Ongoing and not Reach Week 48 in ET Phase	0	0	0		
Subjects Evaluable for Analysis of PGIC at Week 48 in ET Phase	43	30	73		
Improvement, n(%)	11 (25.6%)	9 (30.0%)	20 (27.4%)		
Very much improved	4 (9.3%)	0	4 (5.5%)		
Much improved	5 (11.6%)	6 (20.0%)	11 (15.1%)		
Minimally improved	2 (4.7%)	3 (10.0%)	5 (6.8%)		
95% Exact CI	0.1352, 0.4117	0.1473, 0.4940	0.1761, 0.3909		
Worsening, n(%)	5 (11.6%)	3 (10.0%)	8 (11.0%)		
Minimally worse	4 (9.3%)	3 (10.0%)	7 (9.6%)		
Much worse	1 (2.3%)	0	1 (1.4%)		
Very much worse	0	0	0		
95% Exact CI	0.0389, 0.2508	0.0211, 0.2653	0.0485, 0.2046		
Missing Assessment	25 (58.1%)	16 (53.3%)	41 (56.2%)		
No change	2 (4.7%)	2 (6.7%)	4 (5.5%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-pgic-ext.sas V.03.05 Output file: t-chg-pgic-ext.pdf 24AUG2023:16:54

Table 2.7901: Analysis of Patient Global Impression of Change
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	ET Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 43)	Switch (BAT->MMB) (N = 30)	Total (N = 73)	MMB in RT (N = 66)	Total (N = 96)
Week 60 in Extended Treatment Phase, n(%)					
Subjects Ongoing and not Reach Week 60 in ET Phase	0	0	0		
Subjects Evaluable for Analysis of PGIC at Week 60 in ET Phase	43	30	73		
Improvement, n(%)	11 (25.6%)	6 (20.0%)	17 (23.3%)		
Very much improved	1 (2.3%)	0	1 (1.4%)		
Much improved	7 (16.3%)	4 (13.3%)	11 (15.1%)		
Minimally improved	3 (7.0%)	2 (6.7%)	5 (6.8%)		
95% Exact CI	0.1352, 0.4117	0.0771, 0.3857	0.1419, 0.3465		
Worsening, n(%)	4 (9.3%)	2 (6.7%)	6 (8.2%)		
Minimally worse	3 (7.0%)	2 (6.7%)	5 (6.8%)		
Much worse	1 (2.3%)	0	1 (1.4%)		
Very much worse	0	0	0		
95% Exact CI	0.0259, 0.2214	0.0082, 0.2207	0.0308, 0.1704		
Missing Assessment	27 (62.8%)	20 (66.7%)	47 (64.4%)		
No change	1 (2.3%)	2 (6.7%)	3 (4.1%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification

Table 2.7901: Analysis of Patient Global Impression of Change
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	ET Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 43)	Switch (BAT->MMB) (N = 30)	Total (N = 73)	MMB in RT (N = 66)	Total (N = 96)
Week 72 in Extended Treatment Phase, n(%)					
Subjects Ongoing and not Reach Week 72 in ET Phase	0	0	0		
Subjects Evaluable for Analysis of PGIC at Week 72 in ET Phase	43	30	73		
Improvement, n(%)	11 (25.6%)	9 (30.0%)	20 (27.4%)		
Very much improved	1 (2.3%)	0	1 (1.4%)		
Much improved	7 (16.3%)	5 (16.7%)	12 (16.4%)		
Minimally improved	3 (7.0%)	4 (13.3%)	7 (9.6%)		
95% Exact CI	0.1352, 0.4117	0.1473, 0.4940	0.1761, 0.3909		
Worsening, n(%)	1 (2.3%)	1 (3.3%)	2 (2.7%)		
Minimally worse	1 (2.3%)	0	1 (1.4%)		
Much worse	0	0	0		
Very much worse	0	1 (3.3%)	1 (1.4%)		
95% Exact CI	0.0006, 0.1229	0.0008, 0.1722	0.0033, 0.0955		
Missing Assessment	30 (69.8%)	19 (63.3%)	49 (67.1%)		
No change	1 (2.3%)	1 (3.3%)	2 (2.7%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification

Table 2.7901: Analysis of Patient Global Impression of Change
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	ET Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 43)	Switch (BAT->MMB) (N = 30)	Total (N = 73)	MMB in RT (N = 66)	Total (N = 96)
Week 84 in Extended Treatment Phase, n(%)					
Subjects Ongoing and not Reach Week 84 in ET Phase	0	0	0		
Subjects Evaluable for Analysis of PGIC at Week 84 in ET Phase	43	30	73		
Improvement, n(%)	6 (14.0%)	9 (30.0%)	15 (20.5%)		
Very much improved	0	0	0		
Much improved	4 (9.3%)	5 (16.7%)	9 (12.3%)		
Minimally improved	2 (4.7%)	4 (13.3%)	6 (8.2%)		
95% Exact CI	0.0530, 0.2793	0.1473, 0.4940	0.1198, 0.3162		
Worsening, n(%)	1 (2.3%)	0	1 (1.4%)		
Minimally worse	1 (2.3%)	0	1 (1.4%)		
Much worse	0	0	0		
Very much worse	0	0	0		
95% Exact CI	0.0006, 0.1229	0.0000, 0.1157	0.0003, 0.0740		
Missing Assessment	35 (81.4%)	20 (66.7%)	55 (75.3%)		
No change	1 (2.3%)	1 (3.3%)	2 (2.7%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification

Data Extracted: CRF data: 25JUN2019

Table 2.7901: Analysis of Patient Global Impression of Change
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	ET Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 43)	Switch (BAT->MMB) (N = 30)	Total (N = 73)	MMB in RT (N = 66)	Total (N = 96)
Week 96 in Extended Treatment Phase, n(%)					
Subjects Ongoing and not Reach Week 96 in ET Phase	0	0	0		
Subjects Evaluable for Analysis of PGIC at Week 96 in ET Phase	43	30	73		
Improvement, n(%)	5 (11.6%)	5 (16.7%)	10 (13.7%)		
Very much improved	2 (4.7%)	0	2 (2.7%)		
Much improved	2 (4.7%)	4 (13.3%)	6 (8.2%)		
Minimally improved	1 (2.3%)	1 (3.3%)	2 (2.7%)		
95% Exact CI	0.0389, 0.2508	0.0564, 0.3472	0.0677, 0.2375		
Worsening, n(%)	1 (2.3%)	1 (3.3%)	2 (2.7%)		
Minimally worse	1 (2.3%)	0	1 (1.4%)		
Much worse	0	0	0		
Very much worse	0	1 (3.3%)	1 (1.4%)		
95% Exact CI	0.0006, 0.1229	0.0008, 0.1722	0.0033, 0.0955		
Missing Assessment	37 (86.0%)	21 (70.0%)	58 (79.5%)		
No change	0	3 (10.0%)	3 (4.1%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-pgic-ext.sas V.03.05 Output file: t-chg-pgic-ext.pdf 24AUG2023:16:54

Table 2.7901: Analysis of Patient Global Impression of Change
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	ET Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 43)	Switch (BAT->MMB) (N = 30)	Total (N = 73)	MMB in RT (N = 66)	Total (N = 96)
Week 108 in Extended Treatment Phase, n(%)					
Subjects Ongoing and not Reach Week 108 in ET Phase	0	0	0		
Subjects Evaluable for Analysis of PGIC at Week 108 in ET Phase	43	30	73		
Improvement, n(%)	2 (4.7%)	7 (23.3%)	9 (12.3%)		
Very much improved	1 (2.3%)	0	1 (1.4%)		
Much improved	1 (2.3%)	3 (10.0%)	4 (5.5%)		
Minimally improved	0	4 (13.3%)	4 (5.5%)		
95% Exact CI	0.0057, 0.1581	0.0993, 0.4228	0.0580, 0.2212		
Worsening, n(%)	1 (2.3%)	0	1 (1.4%)		
Minimally worse	1 (2.3%)	0	1 (1.4%)		
Much worse	0	0	0		
Very much worse	0	0	0		
95% Exact CI	0.0006, 0.1229	0.0000, 0.1157	0.0003, 0.0740		
Missing Assessment	38 (88.4%)	22 (73.3%)	60 (82.2%)		
No change	2 (4.7%)	1 (3.3%)	3 (4.1%)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification

Data Extracted: CRF data: 25JUN2019

Table 2.7901: Analysis of Patient Global Impression of Change
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	ET Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 43)	Switch (BAT->MMB) (N = 30)	Total (N = 73)	MMB in RT (N = 66)	Total (N = 96)
Week 120 in Extended Treatment Phase, n(%)					
Subjects Ongoing and not Reach Week 120 in ET Phase	0	0	0		
Subjects Evaluable for Analysis of PGIC at Week 120 in ET Phase	43	30	73		
Improvement, n(%)	3 (7.0%)	5 (16.7%)	8 (11.0%)		
Very much improved	1 (2.3%)	0	1 (1.4%)		
Much improved	2 (4.7%)	3 (10.0%)	5 (6.8%)		
Minimally improved	0	2 (6.7%)	2 (2.7%)		
95% Exact CI	0.0146, 0.1906	0.0564, 0.3472	0.0485, 0.2046		
Worsening, n(%)	1 (2.3%)	0	1 (1.4%)		
Minimally worse	1 (2.3%)	0	1 (1.4%)		
Much worse	0	0	0		
Very much worse	0	0	0		
95% Exact CI	0.0006, 0.1229	0.0000, 0.1157	0.0003, 0.0740		
Missing Assessment	39 (90.7%)	25 (83.3%)	64 (87.7%)		
No change	0	0	0		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-pgic-ext.sas V.03.05 Output file: t-chg-pgic-ext.pdf 24AUG2023:16:54

Table 2.7901: Analysis of Patient Global Impression of Change
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	ET Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 43)	Switch (BAT->MMB) (N = 30)	Total (N = 73)	MMB in RT (N = 66)	Total (N = 96)
Week 132 in Extended Treatment Phase, n(%)					
Subjects Ongoing and not Reach Week 132 in ET Phase	0	0	0		
Subjects Evaluable for Analysis of PGIC at Week 132 in ET Phase	43	30	73		
Improvement, n(%)	4 (9.3%)	2 (6.7%)	6 (8.2%)		
Very much improved	2 (4.7%)	0	2 (2.7%)		
Much improved	1 (2.3%)	2 (6.7%)	3 (4.1%)		
Minimally improved	1 (2.3%)	0	1 (1.4%)		
95% Exact CI	0.0259, 0.2214	0.0082, 0.2207	0.0308, 0.1704		
Worsening, n(%)	0	0	0		
Minimally worse	0	0	0		
Much worse	0	0	0		
Very much worse	0	0	0		
95% Exact CI	0.0000, 0.0822	0.0000, 0.1157	0.0000, 0.0493		
Missing Assessment	39 (90.7%)	28 (93.3%)	67 (91.8%)		
No change	0	0	0		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-pgic-ext.sas V.03.05 Output file: t-chg-pgic-ext.pdf 24AUG2023:16:54

Table 2.7901: Analysis of Patient Global Impression of Change
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	ET Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 43)	Switch (BAT->MMB) (N = 30)	Total (N = 73)	MMB in RT (N = 66)	Total (N = 96)
Week 144 in Extended Treatment Phase, n(%)					
Subjects Ongoing and not Reach Week 144 in ET Phase	0	0	0		
Subjects Evaluable for Analysis of PGIC at Week 144 in ET Phase	43	30	73		
Improvement, n(%)	2 (4.7%)	2 (6.7%)	4 (5.5%)		
Very much improved	1 (2.3%)	0	1 (1.4%)		
Much improved	1 (2.3%)	2 (6.7%)	3 (4.1%)		
Minimally improved	0	0	0		
95% Exact CI	0.0057, 0.1581	0.0082, 0.2207	0.0151, 0.1344		
Worsening, n(%)	0	0	0		
Minimally worse	0	0	0		
Much worse	0	0	0		
Very much worse	0	0	0		
95% Exact CI	0.0000, 0.0822	0.0000, 0.1157	0.0000, 0.0493		
Missing Assessment	41 (95.3%)	28 (93.3%)	69 (94.5%)		
No change	0	0	0		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-pgic-ext.sas V.03.05 Output file: t-chg-pgic-ext.pdf 24AUG2023:16:54

Table 2.7901: Analysis of Patient Global Impression of Change
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	ET Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 43)	Switch (BAT->MMB) (N = 30)	Total (N = 73)	MMB in RT (N = 66)	Total (N = 96)
Week 156 in Extended Treatment Phase, n(%)					
Subjects Ongoing and not Reach Week 156 in ET Phase	0	0	0		
Subjects Evaluable for Analysis of PGIC at Week 156 in ET Phase	43	30	73		
Improvement, n(%)	0	2 (6.7%)	2 (2.7%)		
Very much improved	0	0	0		
Much improved	0	2 (6.7%)	2 (2.7%)		
Minimally improved	0	0	0		
95% Exact CI	0.0000, 0.0822	0.0082, 0.2207	0.0033, 0.0955		
Worsening, n(%)	0	0	0		
Minimally worse	0	0	0		
Much worse	0	0	0		
Very much worse	0	0	0		
95% Exact CI	0.0000, 0.0822	0.0000, 0.1157	0.0000, 0.0493		
Missing Assessment	43 (100.0%)	28 (93.3%)	71 (97.3%)		
No change	0	0	0		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-chg-pgic-ext.sas V.03.05 Output file: t-chg-pgic-ext.pdf 24AUG2023:16:54

Table 2.7901: Analysis of Patient Global Impression of Change
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
ITT-Anemic Analysis Set

	ET Phase (Week 24 Onward)			Overall Exposed to MMB	
	Continuing (MMB->MMB) (N = 43)	Switch (BAT->MMB) (N = 30)	Total (N = 73)	MMB in RT (N = 66)	Total (N = 96)
Week 168 in Extended Treatment Phase, n(%)					
Subjects Ongoing and not Reach Week 168 in ET Phase	0	0	0		
Subjects Evaluable for Analysis of PGIC at Week 168 in ET Phase	43	30	73		
Improvement, n(%)	0	0	0		
Very much improved	0	0	0		
Much improved	0	0	0		
Minimally improved	0	0	0		
95% Exact CI	0.0000, 0.0822	0.0000, 0.1157	0.0000, 0.0493		
Worsening, n(%)	0	0	0		
Minimally worse	0	0	0		
Much worse	0	0	0		
Very much worse	0	0	0		
95% Exact CI	0.0000, 0.0822	0.0000, 0.1157	0.0000, 0.0493		
Missing Assessment	43 (100.0%)	30 (100.0%)	73 (100.0%)		
No change	0	0	0		

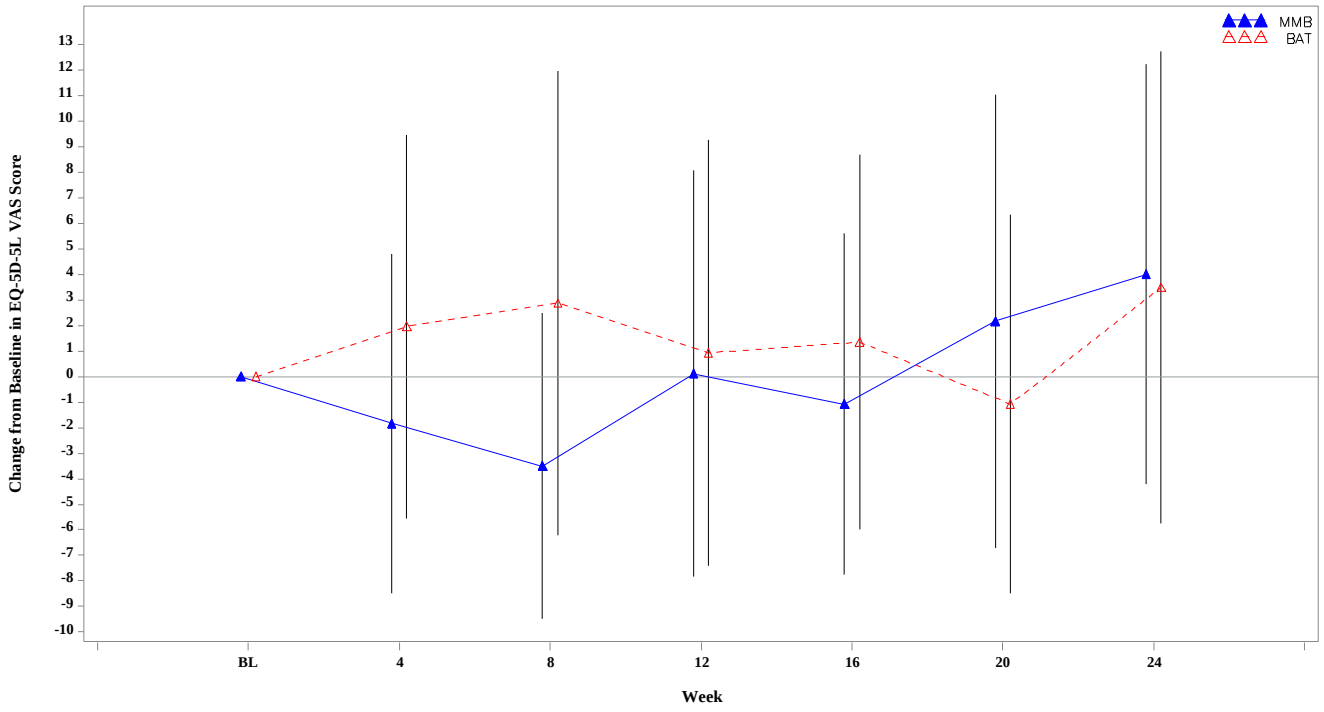
ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification

Data Extracted: CRF data: 25JUN2019

2.8 EQ 5D-VAS

GSK Oncology
Study GS-US-352-1214

Figure 2.3701: Mean (incl. 95% CI) Plot of Change from Baseline (Including Baseline) in EQ-5D-5L Health State VAS Score Over Time
Randomized Treatment Phase
ITT-Anemic Analysis Set



MMB (n)	50	45	44	37	36	32	27
BAT (n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line.sas V.03.05 Output file: g-eq-line-chg-rt.pdf 24AUG2023:16:52

Table 2.8301: Analysis of EQ-5D-5L VAS Score, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Score at Baseline		
n	50	29
Mean (SD)	57.6 (19.52)	51.3 (19.76)
Median	54.0	50.0
Q1, Q3	41.0, 70.0	40.0, 60.0
Min, Max	20.0, 100.0	10.0, 90.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
Score at Week 4		
n	60	31
Mean (SD)	57.6 (22.15)	52.5 (21.02)
Median	59.0	51.0
Q1, Q3	47.5, 76.5	39.0, 70.0
Min, Max	10.0, 99.0	9.0, 100.0
Return Rate (%)	91%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	91%	84%
Change in Score at Week 4 from Baseline		
n	45	26
Mean (SD)	-1.8 (22.04)	2.0 (18.57)
Median	0.0	4.0
Q1, Q3	-15.0, 11.0	-10.0, 15.0
Min, Max	-45.0, 65.0	-41.0, 30.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
EQ-5D-5L = European Quality of Life 5-Dimension 5-Level (questionnaire).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8301: Analysis of EQ-5D-5L VAS Score, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	47	27	
n [2]	45	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.31 [3.02] (-6.34, 5.71)	0.29 [3.63] (-6.95, 7.54)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.60 [4.72] (-10.02, 8.81)		
MMRM: P-value	0.90		
Corrected Hedges' g (95% CI)	-0.030 (-0.513, 0.452)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.19		
Percent Change in Score at Week 4 from Baseline			
n	45	26	
Mean (SD)	4.5 (53.53)	13.2 (49.64)	
Median	0.0	6.3	
Q1, Q3	-23.1, 18.0	-18.3, 42.0	
Min, Max	-80.0, 216.7	-80.4, 150.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	47	27	
n [2]	45	26	
MMRM: Least Squares Mean [SE] (95% CI)	10.38 [7.31] (-4.20, 24.97)	9.02 [8.71] (-8.36, 26.40)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.36 [11.36] (-21.30, 24.02)		
MMRM: P-value	0.90		
Corrected Hedges' g (95% CI)	0.028 (-0.454, 0.511)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.078		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
EQ-5D-5L = European Quality of Life 5-Dimension 5-Level (questionnaire).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8301: Analysis of EQ-5D-5L VAS Score, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Score at Week 8			
n	57	27	
Mean (SD)	57.5 (22.21)	56.1 (19.67)	
Median	55.0	51.0	
Q1, Q3	40.0, 75.0	49.0, 75.0	
Min, Max	9.0, 100.0	6.0, 90.0	
Return Rate (%)	86%	69%	
Number of Subjects in Risk	61	36	
Return Rate in Risk (%)	93%	75%	
Change in Score at Week 8 from Baseline			
n	44	24	
Mean (SD)	-3.5 (19.66)	2.9 (21.50)	
Median	-0.5	0.5	
Q1, Q3	-18.0, 8.5	-10.0, 17.5	
Min, Max	-69.0, 40.0	-31.0, 50.0	
Difference in Change from Baseline at Week 8			
n [1]	47	27	
n [2]	44	24	
MMRM: Least Squares Mean [SE] (95% CI)	-2.66 [3.11] (-8.87, 3.54)	1.52 [3.81] (-6.09, 9.13)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-4.18 [4.89] (-13.94, 5.58)		
MMRM: P-value	0.40		
Corrected Hedges' g (95% CI)	-0.207 (-0.705, 0.292)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.44		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
EQ-5D-5L = European Quality of Life 5-Dimension 5-Level (questionnaire).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8301: Analysis of EQ-5D-5L VAS Score, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Score at Week 8 from Baseline		
n	44	24
Mean (SD)	-1.3 (43.65)	25.2 (89.74)
Median	-0.5	1.0
Q1, Q3	-25.7, 13.6	-22.5, 26.8
Min, Max	-77.5, 140.0	-60.8, 333.3
Difference in Percent Change from Baseline at Week 8		
n [1]	47	27
n [2]	44	24
MMRM: Least Squares Mean [SE] (95% CI)	3.58 [9.17] (-14.71, 21.88)	20.98 [11.50] (-1.97, 43.93)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-17.40 [14.68] (-46.68, 11.89)	
MMRM: P-value	0.24	
Corrected Hedges' g (95% CI)	-0.290 (-0.790, 0.210)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.27	
Score at Week 12		
n	51	30
Mean (SD)	59.2 (19.91)	53.4 (20.65)
Median	55.0	55.0
Q1, Q3	46.0, 80.0	41.0, 64.0
Min, Max	19.0, 97.0	2.0, 91.0
Return Rate (%)	77%	77%
Number of Subjects in Risk	59	33
Return Rate in Risk (%)	86%	91%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
EQ-5D-5L = European Quality of Life 5-Dimension 5-Level (questionnaire).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8301: Analysis of EQ-5D-5L VAS Score, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Score at Week 12 from Baseline			
n	37	26	
Mean (SD)	0.1 (23.81)	0.9 (20.59)	
Median	0.0	9.5	
Q1, Q3	-18.0, 20.0	-10.0, 11.0	
Min, Max	-44.0, 50.0	-50.0, 31.0	
Difference in Change from Baseline at Week 12			
n [1]	47	27	
n [2]	37	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.37 [3.31] (-6.97, 6.23)	-0.89 [3.82] (-8.52, 6.74)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.53 [5.04] (-9.53, 10.58)		
MMRM: P-value	0.92		
Corrected Hedges' g (95% CI)	0.026 (-0.475, 0.528)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.44		
Percent Change in Score at Week 12 from Baseline			
n	37	26	
Mean (SD)	11.2 (62.12)	11.5 (51.72)	
Median	0.0	13.2	
Q1, Q3	-33.3, 28.6	-16.7, 25.0	
Min, Max	-62.0, 250.0	-80.0, 140.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
EQ-5D-5L = European Quality of Life 5-Dimension 5-Level (questionnaire).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8301: Analysis of EQ-5D-5L VAS Score, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 12			
n [1]	47	27	
n [2]	37	26	
MMRM: Least Squares Mean [SE] (95% CI)	12.64 [8.34] (-4.01, 29.28)	6.91 [9.70] (-12.45, 26.26)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	5.73 [12.76] (-19.72, 31.18)		
MMRM: P-value	0.65		
Corrected Hedges' g (95% CI)	0.113 (-0.389, 0.615)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.49		
Score at Week 16			
n	48	30	
Mean (SD)	56.3 (21.95)	54.1 (19.09)	
Median	50.0	51.5	
Q1, Q3	40.0, 73.0	49.0, 62.0	
Min, Max	14.0, 99.0	7.0, 100.0	
Return Rate (%)	73%	77%	
Number of Subjects in Risk	56	33	
Return Rate in Risk (%)	86%	91%	
Change in Score at Week 16 from Baseline			
n	36	26	
Mean (SD)	-1.1 (19.70)	1.3 (18.17)	
Median	-2.0	5.0	
Q1, Q3	-13.0, 9.5	-9.0, 10.0	
Min, Max	-40.0, 41.0	-42.0, 40.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
EQ-5D-5L = European Quality of Life 5-Dimension 5-Level (questionnaire).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8301: Analysis of EQ-5D-5L VAS Score, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	47	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	-1.36 [3.04] (-7.43, 4.72)	-0.50 [3.42] (-7.32, 6.32)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.86 [4.56] (-9.96, 8.24)		
MMRM: P-value	0.85		
Corrected Hedges' g (95% CI)	-0.047 (-0.552, 0.457)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.61		
Percent Change in Score at Week 16 from Baseline			
n	36	26	
Mean (SD)	4.8 (44.11)	12.6 (51.08)	
Median	-2.7	8.5	
Q1, Q3	-28.5, 25.1	-13.3, 27.5	
Min, Max	-50.0, 133.3	-82.4, 200.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	47	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	6.35 [7.30] (-8.23, 20.92)	8.05 [8.15] (-8.21, 24.32)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.71 [10.90] (-23.46, 20.05)		
MMRM: P-value	0.88		
Corrected Hedges' g (95% CI)	-0.039 (-0.544, 0.465)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.56		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
EQ-5D-5L = European Quality of Life 5-Dimension 5-Level (questionnaire).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8301: Analysis of EQ-5D-5L VAS Score, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Score at Week 20			
n	44	29	
Mean (SD)	58.5 (19.91)	52.8 (21.28)	
Median	50.5	50.0	
Q1, Q3	47.5, 70.0	40.0, 70.0	
Min, Max	21.0, 98.0	4.0, 99.0	
Return Rate (%)	67%	74%	
Number of Subjects in Risk	51	32	
Return Rate in Risk (%)	86%	91%	
Change in Score at Week 20 from Baseline			
n	32	24	
Mean (SD)	2.2 (24.57)	-1.1 (17.52)	
Median	1.0	0.5	
Q1, Q3	-9.0, 20.0	-10.0, 10.0	
Min, Max	-60.0, 45.0	-50.0, 30.0	
Difference in Change from Baseline at Week 20			
n [1]	47	27	
n [2]	32	24	
MMRM: Least Squares Mean [SE] (95% CI)	-0.30 [3.32] (-6.93, 6.32)	-2.61 [3.75] (-10.09, 4.88)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	2.31 [4.99] (-7.66, 12.27)		
MMRM: P-value	0.65		
Corrected Hedges' g (95% CI)	0.122 (-0.408, 0.652)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.28		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
EQ-5D-5L = European Quality of Life 5-Dimension 5-Level (questionnaire).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8301: Analysis of EQ-5D-5L VAS Score, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in Score at Week 20 from Baseline		
n	32	24
Mean (SD)	16.5 (55.83)	7.9 (55.14)
Median	1.3	0.7
Q1, Q3	-24.0, 44.8	-14.2, 23.8
Min, Max	-66.7, 150.0	-83.3, 200.0
Difference in Percent Change from Baseline at Week 20		
n [1]	47	27
n [2]	32	24
MMRM: Least Squares Mean [SE] (95% CI)	12.37 [7.76] (-3.11, 27.85)	3.30 [8.78] (-14.21, 20.82)
MMRM: Least Squares Mean Difference [SE] (95% CI)	9.06 [11.67] (-14.23, 32.36)	
MMRM: P-value	0.44	
Corrected Hedges' g (95% CI)	0.205 (-0.325, 0.736)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.41	
Score at Week 24		
n	41	29
Mean (SD)	60.8 (21.45)	55.6 (22.02)
Median	58.0	53.0
Q1, Q3	49.0, 78.0	45.0, 70.0
Min, Max	9.0, 97.0	7.0, 100.0
Return Rate (%)	62%	74%
Number of Subjects in Risk	48	31
Return Rate in Risk (%)	85%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
EQ-5D-5L = European Quality of Life 5-Dimension 5-Level (questionnaire).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8301: Analysis of EQ-5D-5L VAS Score, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in Score at Week 24 from Baseline			
n	27	23	
Mean (SD)	4.0 (20.75)	3.5 (21.36)	
Median	0.0	0.0	
Q1, Q3	-10.0, 20.0	-10.0, 15.0	
Min, Max	-41.0, 45.0	-42.0, 61.0	
Difference in Change from Baseline at Week 24			
n [1]	47	27	
n [2]	27	23	
MMRM: Least Squares Mean [SE] (95% CI)	1.49 [3.53] (-5.54, 8.53)	2.11 [3.90] (-5.67, 9.90)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.62 [5.24] (-11.08, 9.85)		
MMRM: P-value	0.91		
Corrected Hedges' g (95% CI)	-0.033 (-0.589, 0.523)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.92		
Percent Change in Score at Week 24 from Baseline			
n	27	23	
Mean (SD)	15.5 (53.56)	19.2 (60.48)	
Median	0.0	0.0	
Q1, Q3	-20.0, 42.9	-15.9, 37.3	
Min, Max	-82.0, 160.7	-82.4, 217.9	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
EQ-5D-5L = European Quality of Life 5-Dimension 5-Level (questionnaire).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8301: Analysis of EQ-5D-5L VAS Score, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	47	27	
n [2]	27	23	
MMRM: Least Squares Mean [SE] (95% CI)	12.44 [8.82] (-5.15, 30.04)		14.58 [9.72] (-4.82, 33.98)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.14 [13.09] (-28.26, 23.98)		
MMRM: P-value	0.87		
Corrected Hedges' g (95% CI)	-0.046 (-0.602, 0.511)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.92		

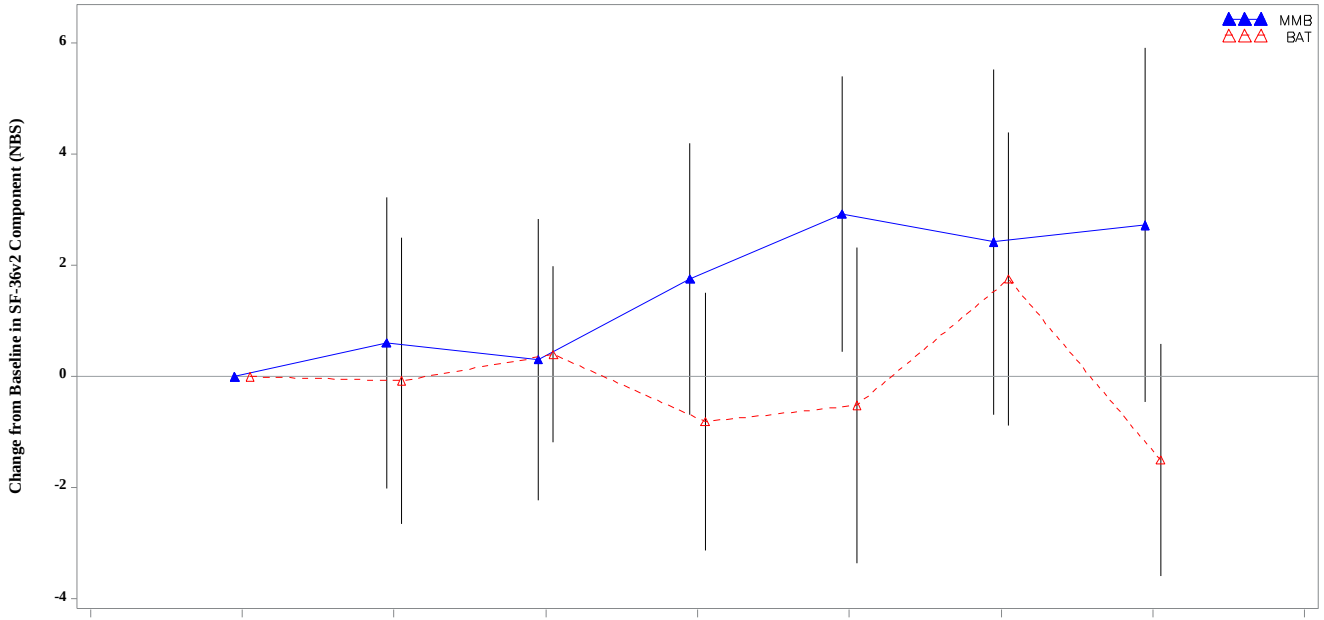
ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
EQ-5D-5L = European Quality of Life 5-Dimension 5-Level (questionnaire).
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

2.9 SF36 v2

GSK Oncology
Study GS-US-352-1214

Figure 2.3601: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in SF-36v2 (for PCS, MCS and Each of the 8 Domains)
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=SF3602-Physical Functioning: NBS



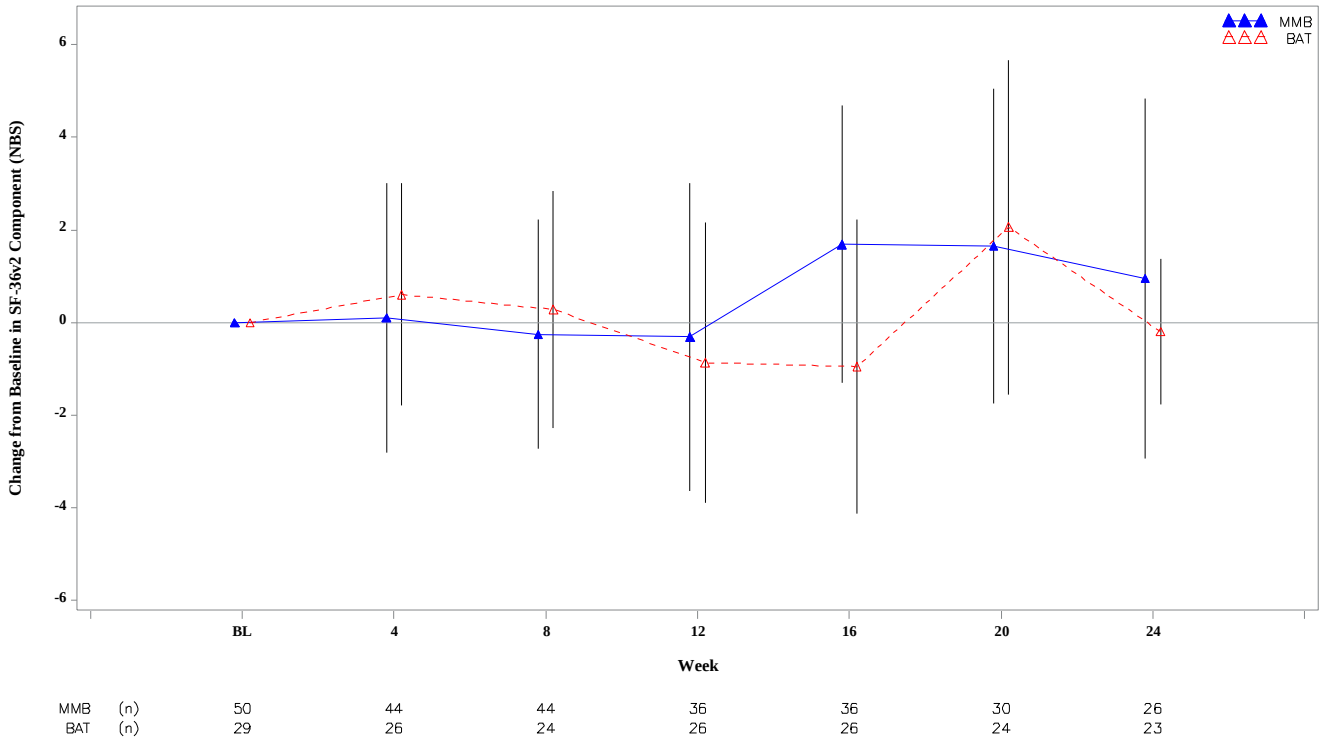
MMB	(n)	50	44	44	36	36	30	26
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line-gba.sas V.03.05 Output file: g-sf-line-chg-rt.pdf 25AUG2023:17:05

Figure 2.3601: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in SF-36v2 (for PCS, MCS and Each of the 8 Domains)
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=SF3602-Role Physical: NBS



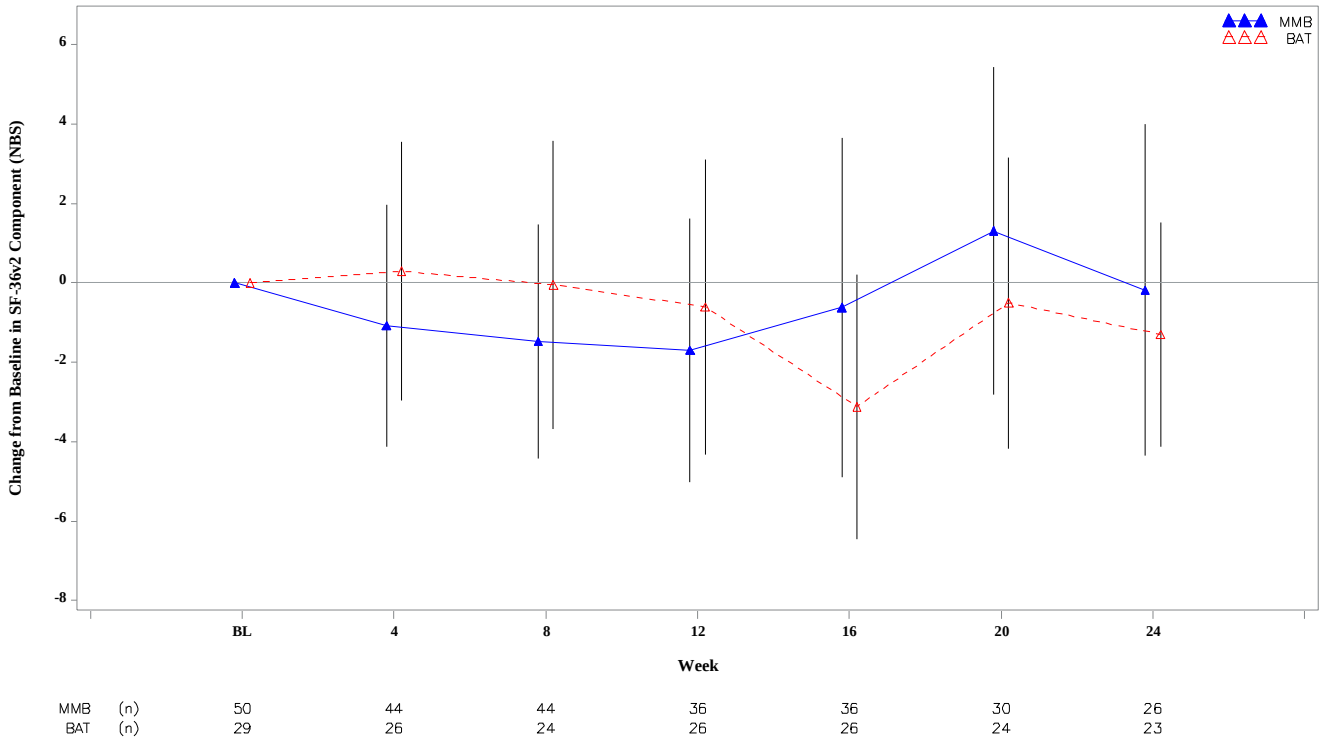
MMB	(n)	50	44	44	36	36	30	26
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line-gba.sas V.03.05 Output file: g-sf-line-chg-rt.pdf 25AUG2023:17:05

Figure 2.3601: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in SF-36v2 (for PCS, MCS and Each of the 8 Domains)
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=SF3602-Bodily Pain: NBS



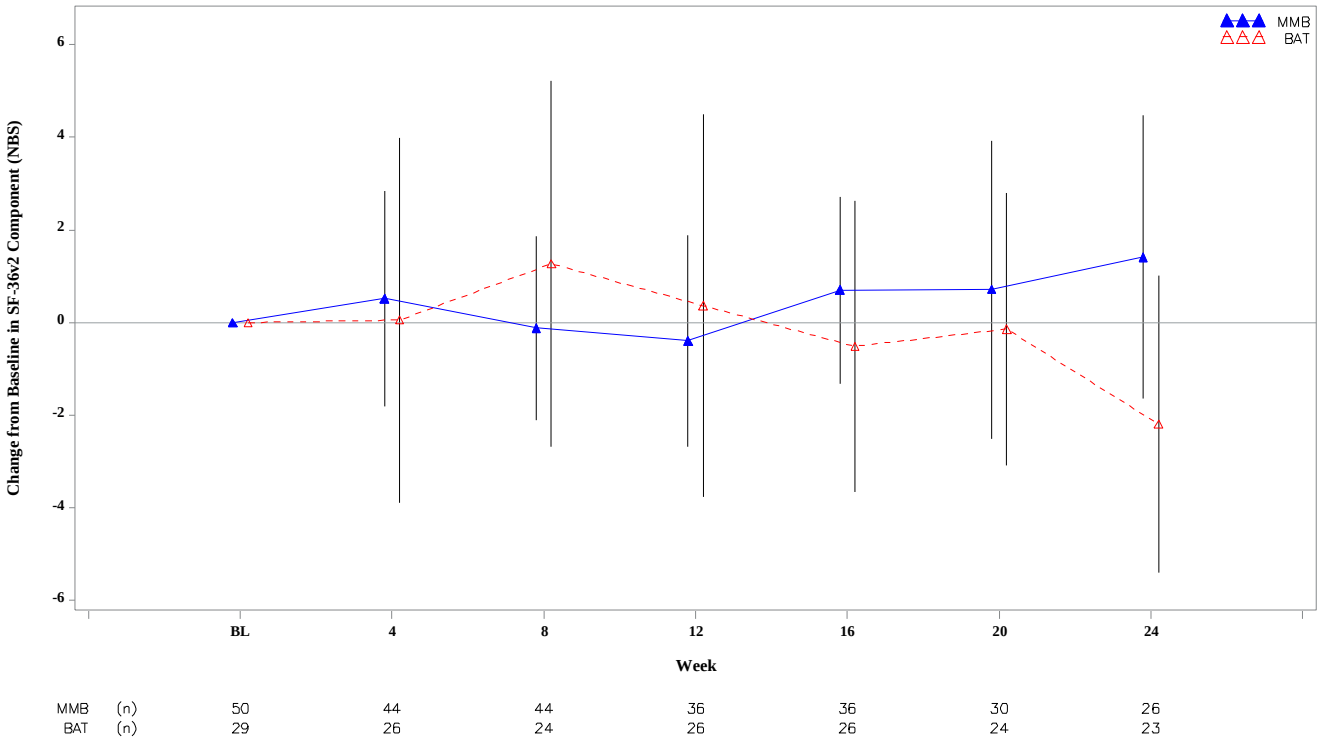
MMB	(n)	50	44	44	36	36	30	26
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line-gba.sas V.03.05 Output file: g-sf-line-chg-rt.pdf 25AUG2023:17:05

Figure 2.3601: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in SF-36v2 (for PCS, MCS and Each of the 8 Domains)
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=SF3602-General Health: NBS



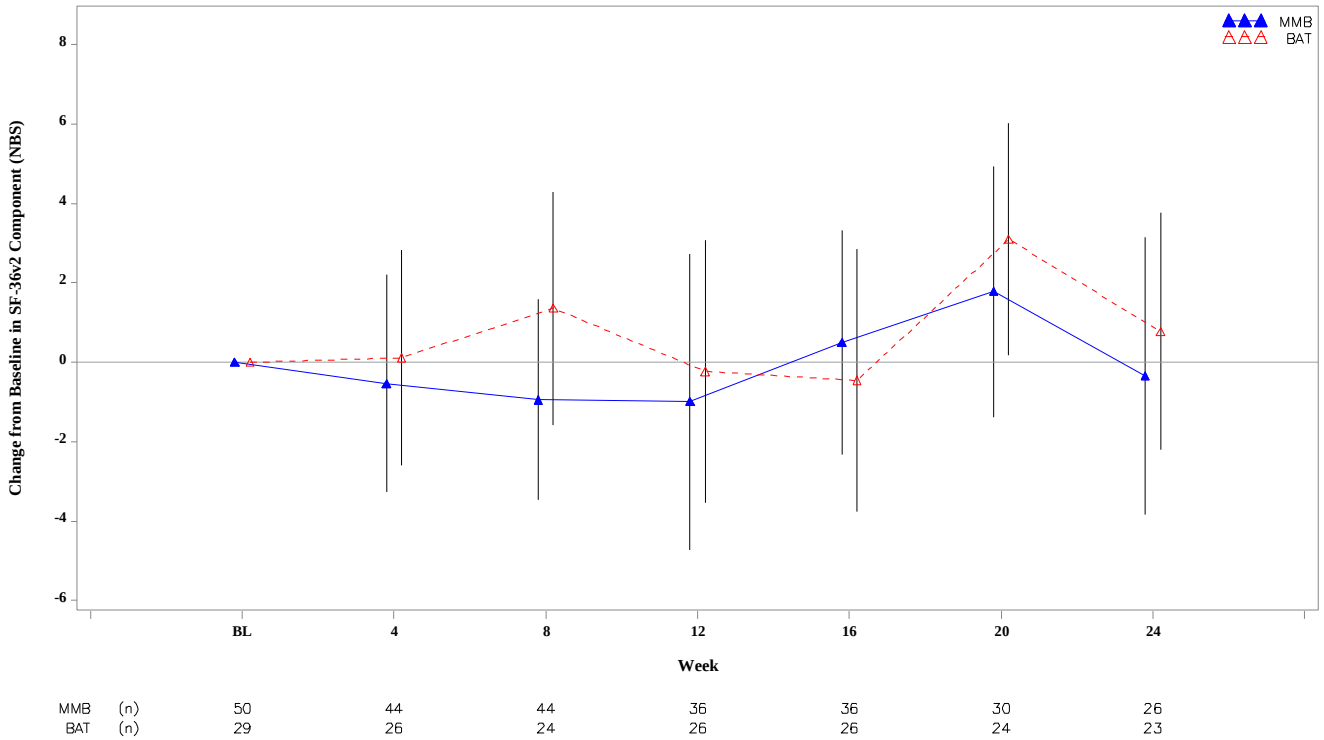
MMB	(n)	50	44	44	36	36	30	26
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line-gba.sas V.03.05 Output file: g-sf-line-chg-rt.pdf 25AUG2023:17:05

Figure 2.3601: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in SF-36v2 (for PCS, MCS and Each of the 8 Domains)
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=SF3602-Vitality: NBS



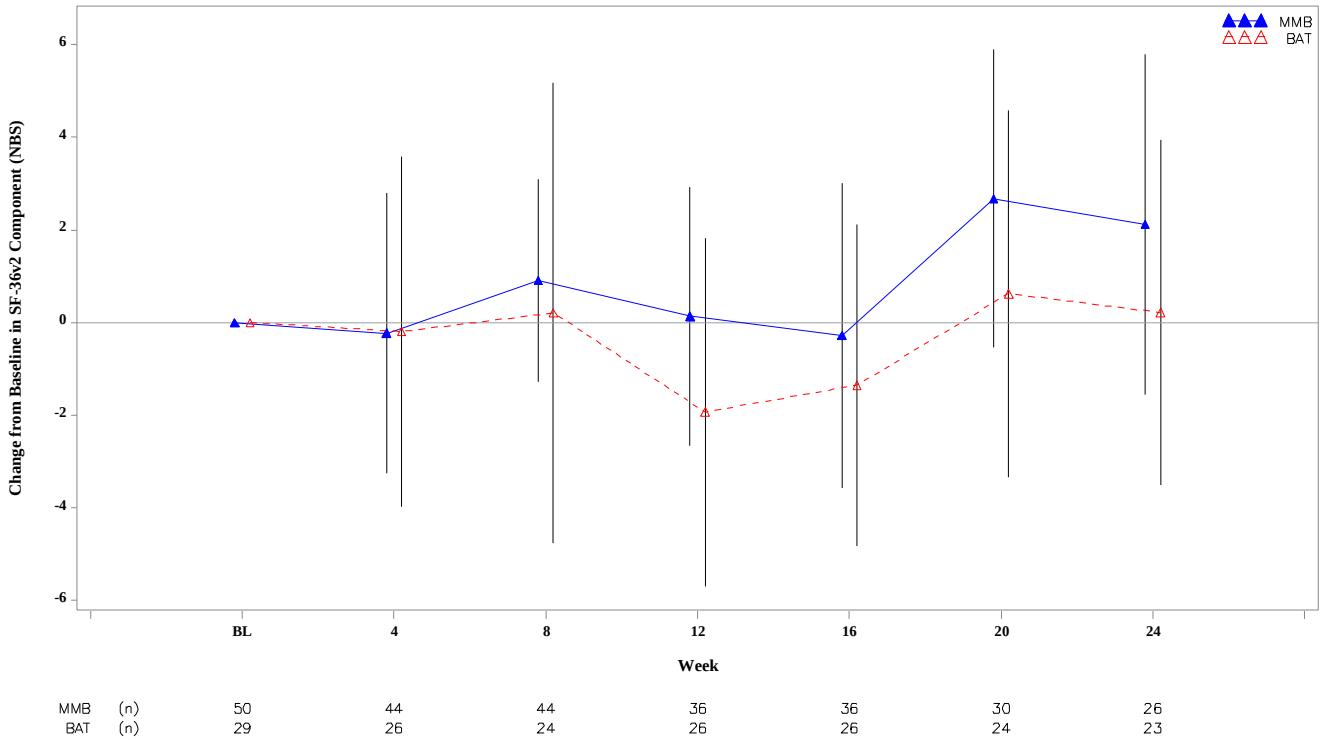
MMB	(n)	50	44	44	36	36	30	26
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line-gba.sas V.03.05 Output file: g-sf-line-chg-rt.pdf 25AUG2023:17:05

Figure 2.3601: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in SF-36v2 (for PCS, MCS and Each of the 8 Domains)
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=SF3602-Social Functioning: NBS



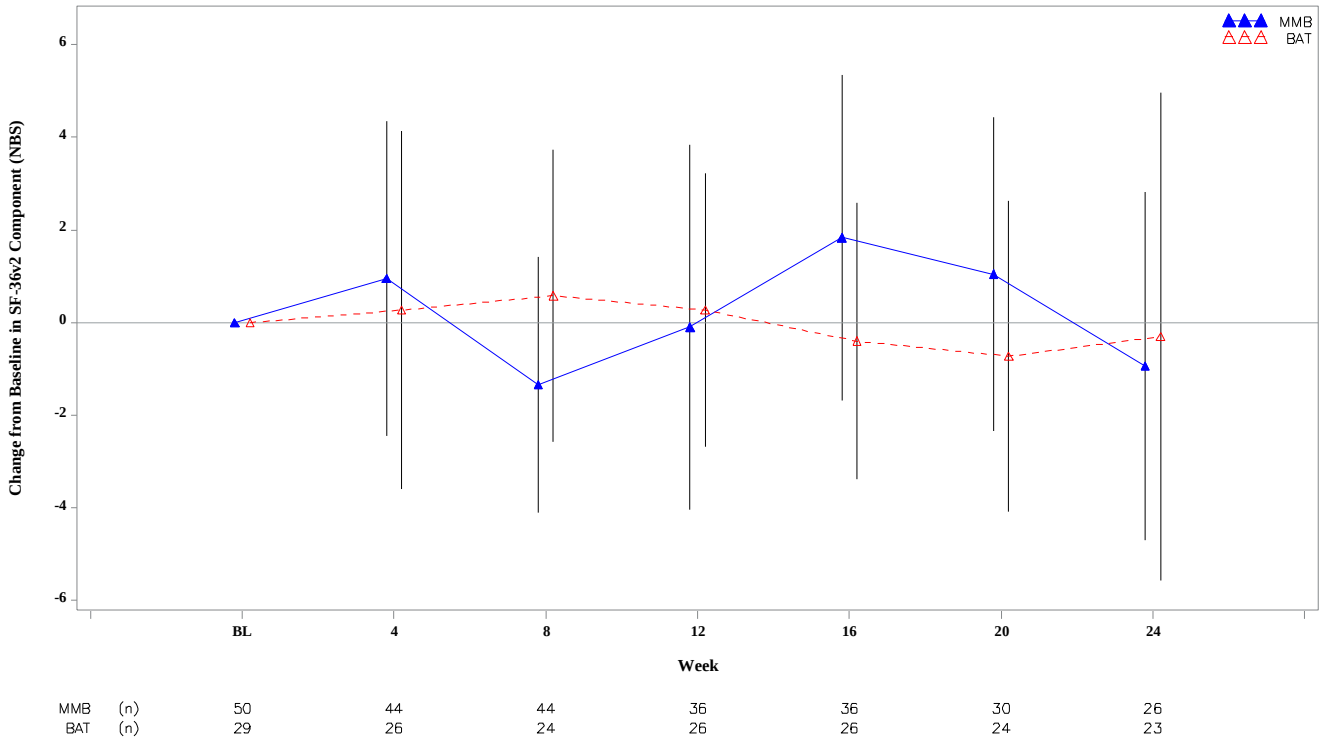
MMB	(n)	50	44	44	36	36	30	26
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line-gba.sas V.03.05 Output file: g-sf-line-chg-rt.pdf 25AUG2023:17:05

Figure 2.3601: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in SF-36v2 (for PCS, MCS and Each of the 8 Domains)
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=SF3602-Role Emotional: NBS



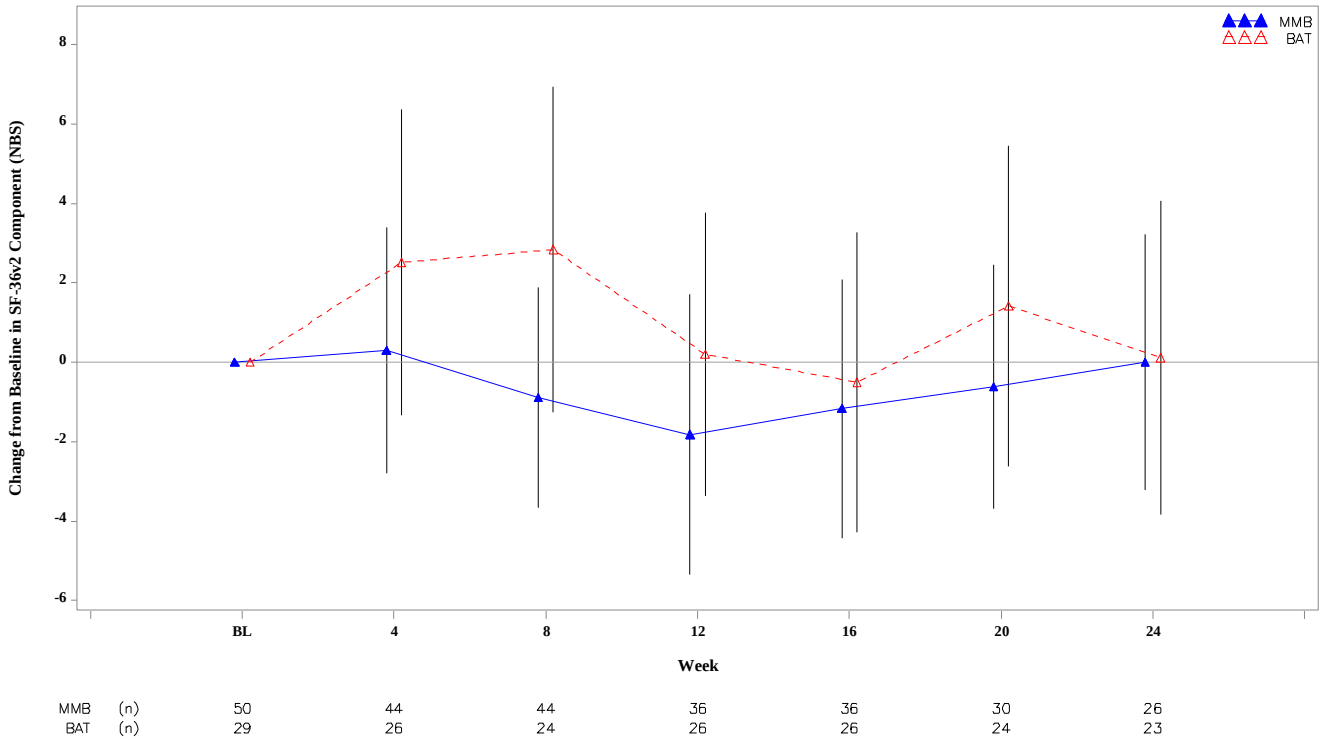
MMB	(n)	50	44	44	36	36	30	26
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line-gba.sas V.03.05 Output file: g-sf-line-chg-rt.pdf 25AUG2023:17:05

Figure 2.3601: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in SF-36v2 (for PCS, MCS and Each of the 8 Domains)
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=SF3602-Mental Health: NBS



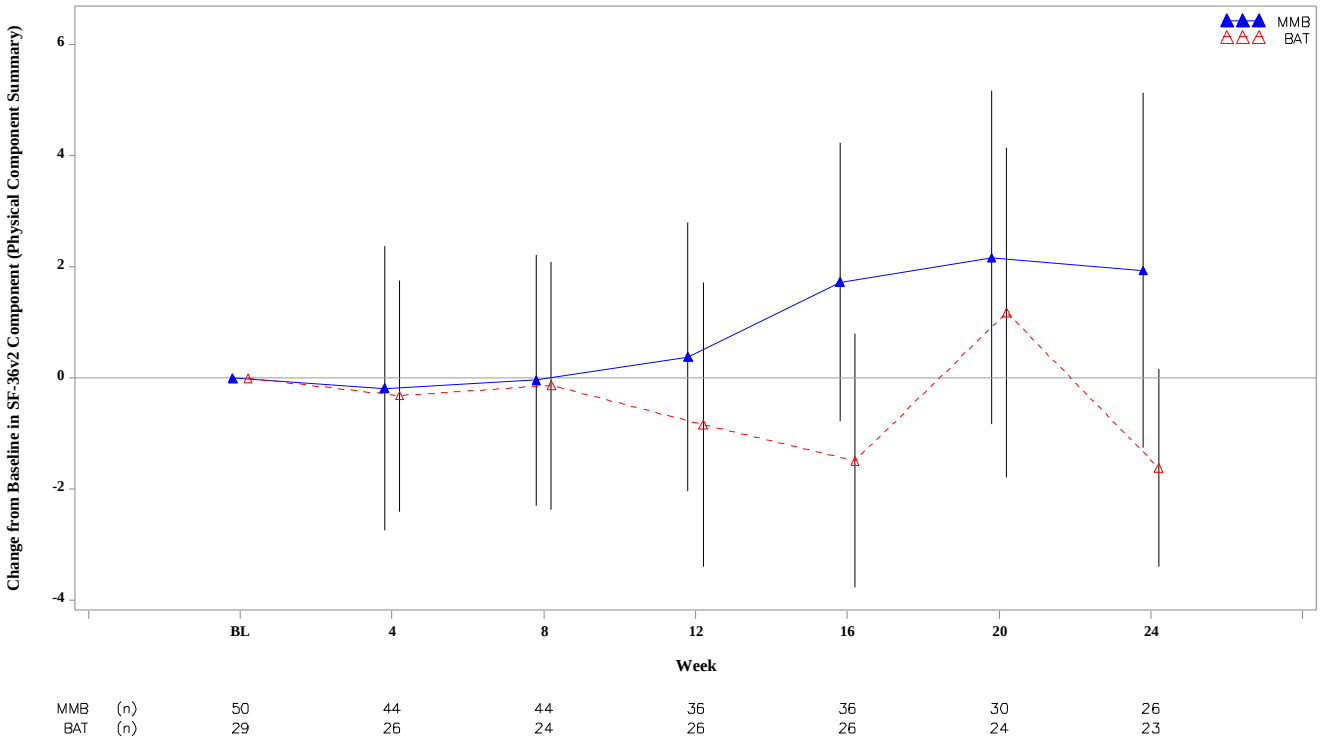
MMB	(n)	50	44	44	36	36	30	26
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line-gba.sas V.03.05 Output file: g-sf-line-chg-rt.pdf 25AUG2023:17:05

Figure 2.3601: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in SF-36v2 (for PCS, MCS and Each of the 8 Domains)
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=SF3602-Physical Component Summary



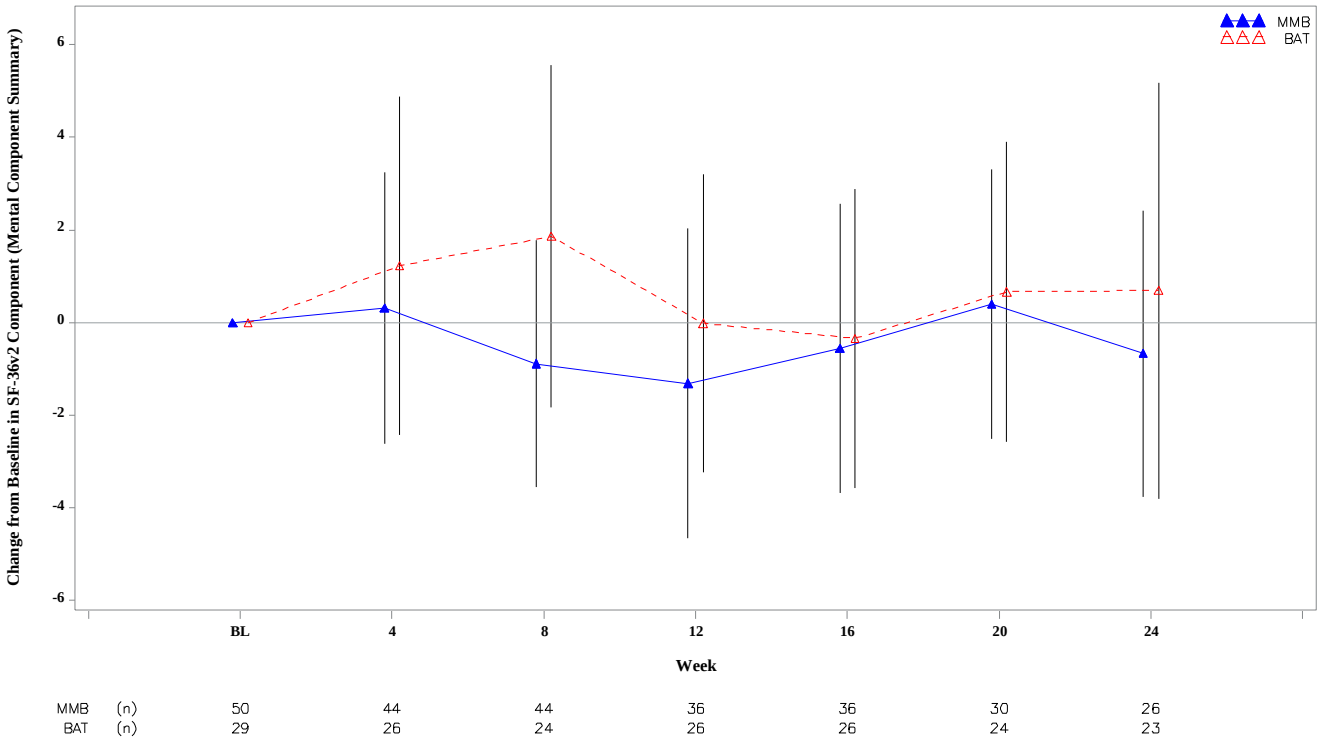
MMB	(n)	50	44	44	36	36	30	26
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line-gba.sas V.03.05 Output file: g-sf-line-chg-rt.pdf 25AUG2023:17:05

Figure 2.3601: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in SF-36v2 (for PCS, MCS and Each of the 8 Domains)
Randomized Treatment Phase
ITT-Anemic Analysis Set

Parameter=SF3602-Mental Component Summary



MMB	(n)	50	44	44	36	36	30	26
BAT	(n)	29	26	24	26	26	24	23

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-spv-line-gba.sas V.03.05 Output file: g-sf-line-chg-rt.pdf 25AUG2023:17:05

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
SF3602-Physical Functioning: NBS at Baseline		
n	50	29
Mean (SD)	37.2 (9.42)	35.0 (9.30)
Median	38.4	32.7
Q1, Q3	28.8, 44.2	26.9, 42.2
Min, Max	19.3, 53.7	21.2, 53.7
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
SF3602-Physical Functioning: NBS at Week 4		
n	57	31
Mean (SD)	38.0 (9.79)	34.8 (7.97)
Median	38.4	34.6
Q1, Q3	30.8, 46.1	28.8, 40.3
Min, Max	21.2, 57.5	19.3, 48.0
Return Rate (%)	86%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	86%	84%
Change in SF3602-Physical Functioning: NBS at Week 4 from Baseline		
n	44	26
Mean (SD)	0.6 (8.63)	-0.1 (6.37)
Median	1.9	0.0
Q1, Q3	-3.8, 6.7	-3.8, 3.8
Min, Max	-30.6, 17.2	-13.4, 9.6

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	46	27	
n [2]	44	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.40 [1.17] (-1.94, 2.74)	-0.45 [1.41] (-3.27, 2.36)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.85 [1.83] (-2.79, 4.50)		
MMRM: P-value	0.64		
Corrected Hedges' g (95% CI)	0.112 (-0.374, 0.597)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.56		
Percent Change in SF3602-Physical Functioning: NBS at Week 4 from Baseline			
n	44	26	
Mean (SD)	4.0 (22.52)	2.1 (19.66)	
Median	3.7	0.0	
Q1, Q3	-8.9, 19.9	-8.7, 14.2	
Min, Max	-57.0, 59.8	-31.7, 45.2	
Difference in Percent Change from Baseline at Week 4			
n [1]	46	27	
n [2]	44	26	
MMRM: Least Squares Mean [SE] (95% CI)	3.98 [3.15] (-2.30, 10.26)	1.01 [3.81] (-6.58, 8.61)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	2.96 [4.92] (-6.86, 12.79)		
MMRM: P-value	0.55		
Corrected Hedges' g (95% CI)	0.144 (-0.341, 0.629)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.59		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
SF3602-Physical Functioning: NBS at Week 8			
n	56	27	
Mean (SD)	37.5 (9.31)	36.4 (9.22)	
Median	36.5	34.6	
Q1, Q3	30.8, 44.2	30.8, 44.2	
Min, Max	19.3, 55.6	21.2, 55.6	
Return Rate (%)	85%	69%	
Number of Subjects in Risk	61	36	
Return Rate in Risk (%)	92%	75%	
Change in SF3602-Physical Functioning: NBS at Week 8 from Baseline			
n	44	24	
Mean (SD)	0.3 (8.32)	0.4 (3.74)	
Median	1.9	1.0	
Q1, Q3	-2.9, 5.7	-1.9, 1.9	
Min, Max	-32.5, 11.5	-5.7, 9.6	
Difference in Change from Baseline at Week 8			
n [1]	46	27	
n [2]	44	24	
MMRM: Least Squares Mean [SE] (95% CI)	-0.22 [1.09] (-2.39, 1.96)	0.10 [1.32] (-2.53, 2.73)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.32 [1.69] (-3.69, 3.06)		
MMRM: P-value	0.85		
Corrected Hedges' g (95% CI)	-0.045 (-0.542, 0.452)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.30		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in SF3602-Physical Functioning: NBS at Week 8 from Baseline			
n	44	24	
Mean (SD)	3.4 (20.89)	1.9 (12.64)	
Median	5.6	1.8	
Q1, Q3	-7.7, 16.3	-6.5, 6.7	
Min, Max	-62.8, 45.9	-19.9, 38.2	
Difference in Percent Change from Baseline at Week 8			
n [1]	46	27	
n [2]	44	24	
MMRM: Least Squares Mean [SE] (95% CI)	2.55 [2.75] (-2.93, 8.04)	0.87 [3.29] (-5.69, 7.44)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.68 [4.24] (-6.78, 10.14)		
MMRM: P-value	0.69		
Corrected Hedges' g (95% CI)	0.095 (-0.403, 0.592)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.32		
SF3602-Physical Functioning: NBS at Week 12			
n	49	30	
Mean (SD)	39.1 (9.89)	35.0 (9.44)	
Median	38.4	35.5	
Q1, Q3	32.7, 46.1	26.9, 42.2	
Min, Max	21.2, 55.6	19.3, 51.8	
Return Rate (%)	74%	77%	
Number of Subjects in Risk	59	33	
Return Rate in Risk (%)	83%	91%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in SF3602-Physical Functioning: NBS at Week 12 from Baseline			
n	36	26	
Mean (SD)	1.8 (7.21)	-0.8 (5.73)	
Median	1.9	-1.0	
Q1, Q3	-1.9, 7.7	-3.8, 1.9	
Min, Max	-15.3, 15.3	-11.5, 11.5	
Difference in Change from Baseline at Week 12			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.60 [1.18] (-1.75, 2.94)	-1.07 [1.36] (-3.77, 1.64)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.67 [1.78] (-1.90, 5.23)		
MMRM: P-value	0.35		
Corrected Hedges' g (95% CI)	0.235 (-0.271, 0.741)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.11		
Percent Change in SF3602-Physical Functioning: NBS at Week 12 from Baseline			
n	36	26	
Mean (SD)	6.4 (20.55)	-1.5 (16.68)	
Median	4.5	-2.2	
Q1, Q3	-6.5, 20.8	-11.1, 5.6	
Min, Max	-39.9, 49.8	-26.5, 45.9	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 12			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	4.56 [3.24] (-1.91, 11.02)		-2.24 [3.77] (-9.76, 5.29)
MMRM: Least Squares Mean Difference [SE] (95% CI)	6.79 [4.95] (-3.08, 16.67)		
MMRM: P-value	0.17		
Corrected Hedges' g (95% CI)	0.347 (-0.161, 0.855)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.068		
SF3602-Physical Functioning: NBS at Week 16			
n	47	30	
Mean (SD)	39.0 (9.98)	36.1 (9.47)	
Median	38.4	37.4	
Q1, Q3	32.7, 49.9	28.8, 40.3	
Min, Max	19.3, 55.6	19.3, 55.6	
Return Rate (%)	71%	77%	
Number of Subjects in Risk	56	33	
Return Rate in Risk (%)	84%	91%	
Change in SF3602-Physical Functioning: NBS at Week 16 from Baseline			
n	36	26	
Mean (SD)	2.9 (7.31)	-0.5 (7.03)	
Median	3.8	0.0	
Q1, Q3	-1.9, 8.6	-5.7, 3.8	
Min, Max	-15.3, 23.0	-13.4, 13.4	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.85 [1.27] (-1.68, 3.37)		-0.78 [1.45] (-3.68, 2.13)
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.62 [1.92] (-2.21, 5.45)		
MMRM: P-value	0.40		
Corrected Hedges' g (95% CI)	0.213 (-0.293, 0.719)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.022		
Percent Change in SF3602-Physical Functioning: NBS at Week 16 from Baseline			
n	36	26	
Mean (SD)	11.0 (26.05)	0.0 (21.83)	
Median	8.6	0.0	
Q1, Q3	-7.3, 22.8	-17.6, 10.5	
Min, Max	-28.5, 119.3	-38.7, 53.5	
Difference in Percent Change from Baseline at Week 16			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	5.55 [3.93] (-2.29, 13.39)		-0.81 [4.59] (-9.97, 8.34)
MMRM: Least Squares Mean Difference [SE] (95% CI)	6.36 [6.02] (-5.66, 18.38)		
MMRM: P-value	0.29		
Corrected Hedges' g (95% CI)	0.267 (-0.239, 0.774)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.022		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
SF3602-Physical Functioning: NBS at Week 20		
n	38	29
Mean (SD)	38.9 (9.45)	36.6 (10.48)
Median	38.4	38.4
Q1, Q3	30.8, 46.1	26.9, 42.2
Min, Max	21.2, 57.5	19.3, 57.5
Return Rate (%)	58%	74%
Number of Subjects in Risk	51	32
Return Rate in Risk (%)	75%	91%
Change in SF3602-Physical Functioning: NBS at Week 20 from Baseline		
n	30	24
Mean (SD)	2.4 (8.32)	1.8 (6.26)
Median	2.9	1.9
Q1, Q3	-3.8, 7.7	-2.9, 5.7
Min, Max	-21.1, 17.2	-7.7, 15.3
Difference in Change from Baseline at Week 20		
n [1]	46	27
n [2]	30	24
MMRM: Least Squares Mean [SE] (95% CI)	-0.23 [1.41] (-3.04, 2.58)	0.65 [1.65] (-2.63, 3.94)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.88 [2.16] (-5.19, 3.43)	
MMRM: P-value	0.68	
Corrected Hedges' g (95% CI)	-0.111 (-0.648, 0.427)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.28	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in SF3602-Physical Functioning: NBS at Week 20 from Baseline			
n	30	24	
Mean (SD)	10.4 (26.19)	5.9 (20.20)	
Median	6.9	4.6	
Q1, Q3	-8.3, 22.2	-9.6, 16.7	
Min, Max	-39.2, 74.6	-28.5, 53.5	
Difference in Percent Change from Baseline at Week 20			
n [1]	46	27	
n [2]	30	24	
MMRM: Least Squares Mean [SE] (95% CI)	3.35 [4.04] (-4.72, 11.42)	3.21 [4.70] (-6.17, 12.59)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.14 [6.18] (-12.20, 12.47)		
MMRM: P-value	0.98		
Corrected Hedges' g (95% CI)	0.006 (-0.531, 0.543)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.37		
SF3602-Physical Functioning: NBS at Week 24			
n	37	29	
Mean (SD)	39.1 (9.17)	34.0 (10.74)	
Median	38.4	30.8	
Q1, Q3	32.7, 46.1	26.9, 40.3	
Min, Max	21.2, 57.5	19.3, 57.5	
Return Rate (%)	56%	74%	
Number of Subjects in Risk	48	31	
Return Rate in Risk (%)	77%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in SF3602-Physical Functioning: NBS at Week 24 from Baseline			
n	26	23	
Mean (SD)	2.7 (7.89)	-1.5 (4.83)	
Median	3.8	0.0	
Q1, Q3	-1.9, 7.7	-3.8, 1.9	
Min, Max	-19.1, 21.1	-13.4, 7.7	
Difference in Change from Baseline at Week 24			
n [1]	46	27	
n [2]	26	23	
MMRM: Least Squares Mean [SE] (95% CI)	1.12 [1.34] (-1.56, 3.79)		-2.76 [1.48] (-5.70, 0.19)
MMRM: Least Squares Mean Difference [SE] (95% CI)	3.87 [1.98] (-0.09, 7.83)		
MMRM: P-value	0.055		
Corrected Hedges' g (95% CI)	0.549 (-0.023, 1.120)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.004		
Percent Change in SF3602-Physical Functioning: NBS at Week 24 from Baseline			
n	26	23	
Mean (SD)	10.7 (26.50)	-4.1 (13.55)	
Median	13.4	0.0	
Q1, Q3	-5.5, 21.7	-11.7, 5.6	
Min, Max	-35.6, 109.3	-41.0, 18.1	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	46	27	
n [2]	26	23	
MMRM: Least Squares Mean [SE] (95% CI)	7.26 [3.92] (-0.56, 15.09)	-7.27 [4.31] (-15.87, 1.33)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	14.53 [5.80] (2.95, 26.11)		
MMRM: P-value	0.015		
Corrected Hedges' g (95% CI)	0.704 (0.126, 1.282)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.007		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
SF3602-Role Physical: NBS at Baseline		
n	50	29
Mean (SD)	36.8 (10.42)	36.4 (10.35)
Median	37.0	34.7
Q1, Q3	30.2, 43.7	28.0, 43.7
Min, Max	21.2, 57.2	21.2, 57.2
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
SF3602-Role Physical: NBS at Week 4		
n	57	31
Mean (SD)	36.9 (10.22)	37.6 (9.15)
Median	39.2	39.2
Q1, Q3	30.2, 43.7	30.2, 43.7
Min, Max	21.2, 57.2	21.2, 57.2
Return Rate (%)	86%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	86%	84%
Change in SF3602-Role Physical: NBS at Week 4 from Baseline		
n	44	26
Mean (SD)	0.1 (9.55)	0.6 (5.94)
Median	0.0	0.0
Q1, Q3	-5.6, 6.7	-4.5, 2.3
Min, Max	-27.0, 15.7	-9.0, 15.7

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	46	27	
n [2]	44	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.07 [1.23] (-2.52, 2.38)		0.97 [1.45] (-1.93, 3.87)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.04 [1.90] (-4.83, 2.76)		
MMRM: P-value	0.59		
Corrected Hedges' g (95% CI)	-0.130 (-0.615, 0.355)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.63		
Percent Change in SF3602-Role Physical: NBS at Week 4 from Baseline			
n	44	26	
Mean (SD)	4.1 (26.31)	3.6 (17.99)	
Median	0.0	0.0	
Q1, Q3	-17.1, 27.2	-8.9, 8.0	
Min, Max	-47.1, 67.0	-21.7, 52.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	46	27	
n [2]	44	26	
MMRM: Least Squares Mean [SE] (95% CI)	4.06 [3.43] (-2.79, 10.92)		4.51 [4.03] (-3.54, 12.57)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.45 [5.30] (-11.02, 10.12)		
MMRM: P-value	0.93		
Corrected Hedges' g (95% CI)	-0.020 (-0.505, 0.465)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.58		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
SF3602-Role Physical: NBS at Week 8		
n	56	27
Mean (SD)	37.1 (9.24)	37.9 (9.67)
Median	37.0	37.0
Q1, Q3	30.2, 45.9	30.2, 43.7
Min, Max	21.2, 57.2	21.2, 57.2
Return Rate (%)	85%	69%
Number of Subjects in Risk	61	36
Return Rate in Risk (%)	92%	75%
Change in SF3602-Role Physical: NBS at Week 8 from Baseline		
n	44	24
Mean (SD)	-0.3 (8.12)	0.3 (6.04)
Median	-1.1	1.1
Q1, Q3	-6.7, 4.5	-2.2, 3.4
Min, Max	-18.0, 18.0	-13.5, 13.5
Difference in Change from Baseline at Week 8		
n [1]	46	27
n [2]	44	24
MMRM: Least Squares Mean [SE] (95% CI)	-0.74 [1.13] (-3.00, 1.52)	0.65 [1.33] (-2.01, 3.31)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.39 [1.74] (-4.86, 2.09)	
MMRM: P-value	0.43	
Corrected Hedges' g (95% CI)	-0.191 (-0.689, 0.308)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.94	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in SF3602-Role Physical: NBS at Week 8 from Baseline		
n	44	24
Mean (SD)	3.2 (25.59)	2.4 (17.21)
Median	-2.2	2.4
Q1, Q3	-12.3, 16.8	-5.4, 10.5
Min, Max	-37.3, 84.6	-38.8, 44.6
Difference in Percent Change from Baseline at Week 8		
n [1]	46	27
n [2]	44	24
MMRM: Least Squares Mean [SE] (95% CI)	2.44 [3.40] (-4.34, 9.22)	3.22 [4.03] (-4.82, 11.26)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.78 [5.25] (-11.25, 9.69)	
MMRM: P-value	0.88	
Corrected Hedges' g (95% CI)	-0.036 (-0.533, 0.462)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.82	
SF3602-Role Physical: NBS at Week 12		
n	49	30
Mean (SD)	37.4 (9.21)	36.9 (8.69)
Median	37.0	38.1
Q1, Q3	30.2, 45.9	30.2, 41.4
Min, Max	21.2, 57.2	21.2, 57.2
Return Rate (%)	74%	77%
Number of Subjects in Risk	59	33
Return Rate in Risk (%)	83%	91%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in SF3602-Role Physical: NBS at Week 12 from Baseline		
n	36	26
Mean (SD)	-0.3 (9.84)	-0.9 (7.49)
Median	0.0	0.0
Q1, Q3	-7.9, 7.9	-4.5, 2.3
Min, Max	-18.0, 18.0	-15.7, 15.7
Difference in Change from Baseline at Week 12		
n [1]	46	27
n [2]	36	26
MMRM: Least Squares Mean [SE] (95% CI)	-0.58 [1.34] (-3.25, 2.09)	-0.26 [1.54] (-3.34, 2.83)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.32 [2.04] (-4.39, 3.74)	
MMRM: P-value	0.87	
Corrected Hedges' g (95% CI)	-0.040 (-0.545, 0.464)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.50	
Percent Change in SF3602-Role Physical: NBS at Week 12 from Baseline		
n	36	26
Mean (SD)	4.1 (30.06)	0.1 (19.98)
Median	0.0	0.0
Q1, Q3	-17.9, 27.1	-9.8, 8.0
Min, Max	-45.8, 84.6	-32.5, 52.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 12			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	4.30 [3.96] (-3.60, 12.19)		1.90 [4.56] (-7.21, 11.01)
MMRM: Least Squares Mean Difference [SE] (95% CI)	2.40 [6.03] (-9.64, 14.43)		
MMRM: P-value	0.69		
Corrected Hedges' g (95% CI)	0.101 (-0.404, 0.605)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.45		
SF3602-Role Physical: NBS at Week 16			
n	47	30	
Mean (SD)	37.5 (9.04)	36.6 (8.36)	
Median	37.0	39.2	
Q1, Q3	30.2, 43.7	30.2, 41.4	
Min, Max	21.2, 57.2	21.2, 57.2	
Return Rate (%)	71%	77%	
Number of Subjects in Risk	56	33	
Return Rate in Risk (%)	84%	91%	
Change in SF3602-Role Physical: NBS at Week 16 from Baseline			
n	36	26	
Mean (SD)	1.7 (8.84)	-1.0 (7.84)	
Median	1.1	0.0	
Q1, Q3	-3.4, 5.6	-6.7, 4.5	
Min, Max	-18.0, 22.5	-15.7, 11.2	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.01 [1.26] (-2.50, 2.51)		-0.39 [1.42] (-3.23, 2.44)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.40 [1.89] (-3.38, 4.17)		
MMRM: P-value	0.83		
Corrected Hedges' g (95% CI)	0.053 (-0.451, 0.558)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.086		
Percent Change in SF3602-Role Physical: NBS at Week 16 from Baseline			
n	36	26	
Mean (SD)	9.9 (31.16)	0.4 (21.37)	
Median	2.0	0.0	
Q1, Q3	-7.7, 21.4	-17.8, 12.9	
Min, Max	-37.3, 105.7	-34.2, 40.2	
Difference in Percent Change from Baseline at Week 16			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	5.58 [3.94] (-2.28, 13.44)		1.99 [4.49] (-6.98, 10.96)
MMRM: Least Squares Mean Difference [SE] (95% CI)	3.59 [5.96] (-8.31, 15.49)		
MMRM: P-value	0.55		
Corrected Hedges' g (95% CI)	0.152 (-0.353, 0.657)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.048		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
SF3602-Role Physical: NBS at Week 20		
n	38	29
Mean (SD)	38.7 (9.66)	38.1 (11.12)
Median	39.2	37.0
Q1, Q3	30.2, 48.2	30.2, 48.2
Min, Max	23.5, 57.2	21.2, 57.2
Return Rate (%)	58%	74%
Number of Subjects in Risk	51	32
Return Rate in Risk (%)	75%	91%
Change in SF3602-Role Physical: NBS at Week 20 from Baseline		
n	30	24
Mean (SD)	1.6 (9.08)	2.1 (8.55)
Median	2.2	3.4
Q1, Q3	-4.5, 6.7	1.1, 6.7
Min, Max	-13.5, 20.2	-22.5, 18.0
Difference in Change from Baseline at Week 20		
n [1]	46	27
n [2]	30	24
MMRM: Least Squares Mean [SE] (95% CI)	-0.01 [1.44] (-2.89, 2.87)	2.20 [1.64] (-1.08, 5.48)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.21 [2.18] (-6.57, 2.15)	
MMRM: P-value	0.32	
Corrected Hedges' g (95% CI)	-0.273 (-0.812, 0.266)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.87	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in SF3602-Role Physical: NBS at Week 20 from Baseline			
n	30	24	
Mean (SD)	9.7 (29.09)	7.3 (23.37)	
Median	7.4	10.0	
Q1, Q3	-12.2, 21.1	2.0, 19.2	
Min, Max	-34.4, 84.6	-51.4, 59.5	
Difference in Percent Change from Baseline at Week 20			
n [1]	46	27	
n [2]	30	24	
MMRM: Least Squares Mean [SE] (95% CI)	5.47 [4.12] (-2.74, 13.69)	7.69 [4.69] (-1.67, 17.04)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.22 [6.23] (-14.65, 10.21)		
MMRM: P-value	0.72		
Corrected Hedges' g (95% CI)	-0.096 (-0.633, 0.441)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.65		
SF3602-Role Physical: NBS at Week 24			
n	37	29	
Mean (SD)	37.1 (9.08)	35.8 (10.03)	
Median	39.2	32.5	
Q1, Q3	30.2, 41.4	28.0, 43.7	
Min, Max	21.2, 57.2	21.2, 57.2	
Return Rate (%)	56%	74%	
Number of Subjects in Risk	48	31	
Return Rate in Risk (%)	77%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in SF3602-Role Physical: NBS at Week 24 from Baseline			
n	26	23	
Mean (SD)	1.0 (9.63)	-0.2 (3.64)	
Median	0.0	0.0	
Q1, Q3	-6.7, 4.5	-2.3, 2.2	
Min, Max	-18.0, 20.2	-6.7, 6.7	
Difference in Change from Baseline at Week 24			
n [1]	46	27	
n [2]	26	23	
MMRM: Least Squares Mean [SE] (95% CI)	-0.35 [1.27] (-2.89, 2.19)	-1.06 [1.38] (-3.81, 1.69)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.71 [1.87] (-3.03, 4.45)		
MMRM: P-value	0.71		
Corrected Hedges' g (95% CI)	0.107 (-0.455, 0.668)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.19		
Percent Change in SF3602-Role Physical: NBS at Week 24 from Baseline			
n	26	23	
Mean (SD)	8.4 (33.39)	-0.3 (10.72)	
Median	0.0	0.0	
Q1, Q3	-14.0, 19.1	-8.0, 4.9	
Min, Max	-37.3, 95.2	-19.4, 22.3	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	46	27	
n [2]	26	23	
MMRM: Least Squares Mean [SE] (95% CI)	4.58 [3.97] (-3.35, 12.51)		-2.43 [4.34] (-11.10, 6.24)
MMRM: Least Squares Mean Difference [SE] (95% CI)	7.01 [5.87] (-4.71, 18.74)		
MMRM: P-value	0.24		
Corrected Hedges' g (95% CI)	0.336 (-0.229, 0.901)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.16		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
SF3602-Bodily Pain: NBS at Baseline		
n	50	29
Mean (SD)	45.8 (10.26)	42.8 (10.12)
Median	46.7	38.6
Q1, Q3	38.2, 51.5	38.2, 50.7
Min, Max	26.5, 62.0	26.5, 62.0
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
SF3602-Bodily Pain: NBS at Week 4		
n	57	31
Mean (SD)	45.9 (10.55)	44.5 (11.75)
Median	42.6	46.7
Q1, Q3	38.2, 55.6	34.2, 51.5
Min, Max	26.5, 62.0	26.5, 62.0
Return Rate (%)	86%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	86%	84%
Change in SF3602-Bodily Pain: NBS at Week 4 from Baseline		
n	44	26
Mean (SD)	-1.1 (10.00)	0.3 (8.04)
Median	0.0	0.0
Q1, Q3	-4.8, 4.0	-6.5, 4.0
Min, Max	-27.8, 15.7	-16.5, 15.3

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	46	27	
n [2]	44	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.31 [1.39] (-3.08, 2.47)		-0.72 [1.68] (-4.07, 2.64)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.41 [2.17] (-3.91, 4.74)		
MMRM: P-value	0.85		
Corrected Hedges' g (95% CI)	0.046 (-0.439, 0.530)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.54		
Percent Change in SF3602-Bodily Pain: NBS at Week 4 from Baseline			
n	44	26	
Mean (SD)	-0.3 (20.35)	2.0 (20.83)	
Median	0.0	0.0	
Q1, Q3	-11.9, 11.6	-13.2, 9.5	
Min, Max	-44.9, 46.0	-32.6, 44.1	
Difference in Percent Change from Baseline at Week 4			
n [1]	46	27	
n [2]	44	26	
MMRM: Least Squares Mean [SE] (95% CI)	1.92 [3.05] (-4.17, 8.02)		0.04 [3.67] (-7.28, 7.36)
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.88 [4.74] (-7.58, 11.35)		
MMRM: P-value	0.69		
Corrected Hedges' g (95% CI)	0.095 (-0.391, 0.580)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.33		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
SF3602-Bodily Pain: NBS at Week 8		
n	56	27
Mean (SD)	44.8 (11.37)	45.1 (11.44)
Median	42.2	42.6
Q1, Q3	34.4, 55.6	38.2, 55.6
Min, Max	25.7, 62.0	26.5, 62.0
Return Rate (%)	85%	69%
Number of Subjects in Risk	61	36
Return Rate in Risk (%)	92%	75%
Change in SF3602-Bodily Pain: NBS at Week 8 from Baseline		
n	44	24
Mean (SD)	-1.5 (9.66)	-0.1 (8.57)
Median	0.0	0.0
Q1, Q3	-8.9, 4.2	-5.4, 6.4
Min, Max	-23.8, 21.4	-16.5, 13.3
Difference in Change from Baseline at Week 8		
n [1]	46	27
n [2]	44	24
MMRM: Least Squares Mean [SE] (95% CI)	-0.62 [1.41] (-3.42, 2.19)	-0.94 [1.72] (-4.38, 2.51)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.32 [2.21] (-4.09, 4.73)	
MMRM: P-value	0.88	
Corrected Hedges' g (95% CI)	0.035 (-0.462, 0.533)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.82	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in SF3602-Bodily Pain: NBS at Week 8 from Baseline		
n	44	24
Mean (SD)	-1.3 (21.58)	1.7 (21.61)
Median	0.0	0.0
Q1, Q3	-18.1, 11.8	-11.8, 15.3
Min, Max	-44.9, 62.5	-32.6, 45.6
Difference in Percent Change from Baseline at Week 8		
n [1]	46	27
n [2]	44	24
MMRM: Least Squares Mean [SE] (95% CI)	1.06 [3.22] (-5.37, 7.49)	-0.43 [3.95] (-8.32, 7.46)
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.49 [5.07] (-8.62, 11.61)	
MMRM: P-value	0.77	
Corrected Hedges' g (95% CI)	0.071 (-0.426, 0.569)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.95	
SF3602-Bodily Pain: NBS at Week 12		
n	49	30
Mean (SD)	46.6 (10.39)	42.6 (9.35)
Median	46.7	42.2
Q1, Q3	38.2, 55.6	38.2, 51.5
Min, Max	26.5, 62.0	26.5, 62.0
Return Rate (%)	74%	77%
Number of Subjects in Risk	59	33
Return Rate in Risk (%)	83%	91%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in SF3602-Bodily Pain: NBS at Week 12 from Baseline			
n	36	26	
Mean (SD)	-1.7 (9.79)	-0.6 (9.22)	
Median	0.0	0.0	
Q1, Q3	-8.5, 5.0	-7.7, 4.0	
Min, Max	-19.8, 20.2	-16.9, 23.4	
Difference in Change from Baseline at Week 12			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.32 [1.45] (-3.21, 2.56)	-1.27 [1.60] (-4.47, 1.93)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.95 [2.14] (-3.32, 5.22)		
MMRM: P-value	0.66		
Corrected Hedges' g (95% CI)	0.110 (-0.394, 0.615)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.50		
Percent Change in SF3602-Bodily Pain: NBS at Week 12 from Baseline			
n	36	26	
Mean (SD)	-1.3 (22.50)	1.3 (24.50)	
Median	0.0	0.0	
Q1, Q3	-16.3, 11.7	-16.9, 10.4	
Min, Max	-37.2, 76.0	-32.9, 76.5	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 12			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	2.68 [3.53] (-4.37, 9.73)		-0.10 [4.01] (-8.11, 7.90)
MMRM: Least Squares Mean Difference [SE] (95% CI)	2.78 [5.30] (-7.80, 13.37)		
MMRM: P-value	0.60		
Corrected Hedges' g (95% CI)	0.132 (-0.373, 0.637)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.38		
SF3602-Bodily Pain: NBS at Week 16			
n	47	30	
Mean (SD)	46.3 (11.01)	42.2 (10.72)	
Median	46.7	42.6	
Q1, Q3	38.2, 55.6	34.2, 50.7	
Min, Max	25.7, 62.0	25.7, 62.0	
Return Rate (%)	71%	77%	
Number of Subjects in Risk	56	33	
Return Rate in Risk (%)	84%	91%	
Change in SF3602-Bodily Pain: NBS at Week 16 from Baseline			
n	36	26	
Mean (SD)	-0.6 (12.64)	-3.1 (8.25)	
Median	-4.0	0.0	
Q1, Q3	-7.9, 3.8	-4.8, 0.0	
Min, Max	-23.8, 35.5	-27.8, 12.1	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.17 [1.63] (-3.09, 3.43)		-3.83 [1.84] (-7.51, -0.15)
MMRM: Least Squares Mean Difference [SE] (95% CI)	4.00 [2.45] (-0.88, 8.89)		
MMRM: P-value	0.11		
Corrected Hedges' g (95% CI)	0.410 (-0.099, 0.920)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.30		
Percent Change in SF3602-Bodily Pain: NBS at Week 16 from Baseline			
n	36	26	
Mean (SD)	2.7 (34.35)	-5.7 (17.46)	
Median	-8.0	0.0	
Q1, Q3	-17.1, 10.5	-11.7, 0.0	
Min, Max	-38.4, 133.8	-44.9, 39.6	
Difference in Percent Change from Baseline at Week 16			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	4.29 [4.29] (-4.27, 12.85)		-7.14 [4.93] (-16.99, 2.70)
MMRM: Least Squares Mean Difference [SE] (95% CI)	11.43 [6.50] (-1.55, 24.41)		
MMRM: P-value	0.083		
Corrected Hedges' g (95% CI)	0.443 (-0.068, 0.953)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.27		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
SF3602-Bodily Pain: NBS at Week 20		
n	38	29
Mean (SD)	48.5 (10.33)	44.2 (9.58)
Median	46.7	42.2
Q1, Q3	42.2, 62.0	38.2, 50.7
Min, Max	30.6, 62.0	30.6, 62.0
Return Rate (%)	58%	74%
Number of Subjects in Risk	51	32
Return Rate in Risk (%)	75%	91%
Change in SF3602-Bodily Pain: NBS at Week 20 from Baseline		
n	30	24
Mean (SD)	1.3 (11.04)	-0.5 (8.69)
Median	0.0	0.0
Q1, Q3	-4.0, 8.1	-4.4, 2.2
Min, Max	-23.8, 19.4	-23.8, 17.3
Difference in Change from Baseline at Week 20		
n [1]	46	27
n [2]	30	24
MMRM: Least Squares Mean [SE] (95% CI)	2.31 [1.57] (-0.82, 5.45)	-0.93 [1.74] (-4.40, 2.54)
MMRM: Least Squares Mean Difference [SE] (95% CI)	3.24 [2.33] (-1.40, 7.88)	
MMRM: P-value	0.17	
Corrected Hedges' g (95% CI)	0.373 (-0.168, 0.914)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.11	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in SF3602-Bodily Pain: NBS at Week 20 from Baseline		
n	30	24
Mean (SD)	6.0 (25.14)	1.2 (21.07)
Median	0.0	0.0
Q1, Q3	-10.6, 22.2	-10.9, 5.2
Min, Max	-38.4, 60.8	-38.4, 60.8
Difference in Percent Change from Baseline at Week 20		
n [1]	46	27
n [2]	30	24
MMRM: Least Squares Mean [SE] (95% CI)	7.65 [3.54] (0.58, 14.72)	0.22 [3.94] (-7.64, 8.08)
MMRM: Least Squares Mean Difference [SE] (95% CI)	7.43 [5.26] (-3.07, 17.93)	
MMRM: P-value	0.16	
Corrected Hedges' g (95% CI)	0.378 (-0.163, 0.920)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.085	
SF3602-Bodily Pain: NBS at Week 24		
n	37	29
Mean (SD)	46.2 (9.91)	42.9 (10.90)
Median	42.6	42.2
Q1, Q3	38.2, 51.5	30.6, 51.5
Min, Max	30.6, 62.0	26.5, 62.0
Return Rate (%)	56%	74%
Number of Subjects in Risk	48	31
Return Rate in Risk (%)	77%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in SF3602-Bodily Pain: NBS at Week 24 from Baseline			
n	26	23	
Mean (SD)	-0.2 (10.34)	-1.3 (6.53)	
Median	0.0	0.0	
Q1, Q3	-4.8, 4.4	-4.8, 4.0	
Min, Max	-23.8, 19.4	-12.5, 11.3	
Difference in Change from Baseline at Week 24			
n [1]	46	27	
n [2]	26	23	
MMRM: Least Squares Mean [SE] (95% CI)	-0.47 [1.60] (-3.65, 2.72)	-2.50 [1.73] (-5.95, 0.95)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	2.03 [2.34] (-2.63, 6.69)		
MMRM: P-value	0.39		
Corrected Hedges' g (95% CI)	0.244 (-0.319, 0.807)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.30		
Percent Change in SF3602-Bodily Pain: NBS at Week 24 from Baseline			
n	26	23	
Mean (SD)	2.4 (24.52)	-2.7 (14.29)	
Median	0.0	0.0	
Q1, Q3	-11.1, 11.6	-11.7, 10.3	
Min, Max	-39.8, 60.8	-30.6, 22.3	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	46	27	
n [2]	26	23	
MMRM: Least Squares Mean [SE] (95% CI)	2.59 [3.59] (-4.57, 9.75)	-5.05 [3.80] (-12.63, 2.52)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	7.64 [5.19] (-2.71, 18.00)		
MMRM: P-value	0.15		
Corrected Hedges' g (95% CI)	0.412 (-0.155, 0.979)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.27		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
SF3602-General Health: NBS at Baseline		
n	50	29
Mean (SD)	38.3 (9.19)	36.3 (8.27)
Median	36.5	35.6
Q1, Q3	30.8, 43.7	30.8, 41.3
Min, Max	23.7, 57.9	19.0, 53.2
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
SF3602-General Health: NBS at Week 4		
n	57	31
Mean (SD)	40.0 (9.77)	36.9 (7.74)
Median	40.4	38.0
Q1, Q3	33.2, 46.1	33.2, 41.3
Min, Max	21.3, 64.1	21.3, 53.2
Return Rate (%)	86%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	86%	84%
Change in SF3602-General Health: NBS at Week 4 from Baseline		
n	44	26
Mean (SD)	0.5 (7.64)	0.1 (9.75)
Median	0.0	-2.4
Q1, Q3	-4.8, 7.1	-5.7, 7.1
Min, Max	-16.6, 14.3	-19.0, 20.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	46	27	
n [2]	44	26	
MMRM: Least Squares Mean [SE] (95% CI)	1.33 [1.23] (-1.13, 3.79)		-0.46 [1.48] (-3.43, 2.50)
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.79 [1.92] (-2.05, 5.64)		
MMRM: P-value	0.35		
Corrected Hedges' g (95% CI)	0.223 (-0.263, 0.709)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.98		
Percent Change in SF3602-General Health: NBS at Week 4 from Baseline			
n	44	26	
Mean (SD)	3.0 (20.01)	4.6 (29.80)	
Median	0.0	-5.6	
Q1, Q3	-10.5, 19.5	-15.4, 24.3	
Min, Max	-30.0, 40.1	-47.1, 70.2	
Difference in Percent Change from Baseline at Week 4			
n [1]	46	27	
n [2]	44	26	
MMRM: Least Squares Mean [SE] (95% CI)	5.75 [3.53] (-1.31, 12.80)		3.20 [4.28] (-5.35, 11.75)
MMRM: Least Squares Mean Difference [SE] (95% CI)	2.54 [5.54] (-8.52, 13.60)		
MMRM: P-value	0.65		
Corrected Hedges' g (95% CI)	0.110 (-0.375, 0.595)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.91		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
SF3602-General Health: NBS at Week 8			
n	56	27	
Mean (SD)	39.2 (9.55)	37.8 (8.43)	
Median	38.0	38.0	
Q1, Q3	33.2, 46.1	33.2, 43.7	
Min, Max	23.7, 62.7	21.3, 53.2	
Return Rate (%)	85%	69%	
Number of Subjects in Risk	61	36	
Return Rate in Risk (%)	92%	75%	
Change in SF3602-General Health: NBS at Week 8 from Baseline			
n	44	24	
Mean (SD)	-0.1 (6.51)	1.3 (9.34)	
Median	0.0	2.4	
Q1, Q3	-4.8, 4.8	-4.8, 8.8	
Min, Max	-17.6, 11.9	-16.6, 20.0	
Difference in Change from Baseline at Week 8			
n [1]	46	27	
n [2]	44	24	
MMRM: Least Squares Mean [SE] (95% CI)	0.47 [1.17] (-1.86, 2.80)	0.94 [1.40] (-1.85, 3.74)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.47 [1.82] (-4.10, 3.15)		
MMRM: P-value	0.80		
Corrected Hedges' g (95% CI)	-0.063 (-0.560, 0.435)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.65		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in SF3602-General Health: NBS at Week 8 from Baseline		
n	44	24
Mean (SD)	0.8 (17.03)	6.4 (25.91)
Median	0.0	7.4
Q1, Q3	-12.6, 14.3	-11.5, 23.7
Min, Max	-33.1, 40.1	-41.2, 60.1
Difference in Percent Change from Baseline at Week 8		
n [1]	46	27
n [2]	44	24
MMRM: Least Squares Mean [SE] (95% CI)	2.98 [3.15] (-3.31, 9.28)	5.67 [3.78] (-1.87, 13.21)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.69 [4.89] (-12.45, 7.08)	
MMRM: P-value	0.58	
Corrected Hedges' g (95% CI)	-0.132 (-0.630, 0.366)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.62	
SF3602-General Health: NBS at Week 12		
n	49	30
Mean (SD)	39.3 (10.28)	36.8 (10.39)
Median	38.0	35.6
Q1, Q3	30.8, 46.1	28.5, 43.7
Min, Max	21.3, 62.7	21.3, 62.7
Return Rate (%)	74%	77%
Number of Subjects in Risk	59	33
Return Rate in Risk (%)	83%	91%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in SF3602-General Health: NBS at Week 12 from Baseline			
n	36	26	
Mean (SD)	-0.4 (6.73)	0.4 (10.21)	
Median	0.0	0.0	
Q1, Q3	-4.8, 4.8	-7.1, 7.1	
Min, Max	-14.3, 15.2	-16.6, 22.4	
Difference in Change from Baseline at Week 12			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.54 [1.36] (-2.17, 3.25)	0.25 [1.60] (-2.94, 3.43)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.30 [2.09] (-3.88, 4.47)		
MMRM: P-value	0.89		
Corrected Hedges' g (95% CI)	0.036 (-0.469, 0.540)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.85		
Percent Change in SF3602-General Health: NBS at Week 12 from Baseline			
n	36	26	
Mean (SD)	-0.5 (17.88)	3.8 (28.46)	
Median	0.0	0.6	
Q1, Q3	-15.0, 10.9	-20.8, 22.7	
Min, Max	-26.8, 45.8	-41.2, 72.5	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 12			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	2.98 [3.66] (-4.33, 10.28)		3.57 [4.28] (-4.97, 12.12)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.60 [5.61] (-11.80, 10.60)		
MMRM: P-value	0.92		
Corrected Hedges' g (95% CI)	-0.027 (-0.531, 0.478)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.69		
SF3602-General Health: NBS at Week 16			
n	47	30	
Mean (SD)	39.6 (9.63)	36.7 (8.67)	
Median	38.9	38.0	
Q1, Q3	33.2, 46.1	30.8, 43.7	
Min, Max	21.3, 57.9	21.3, 50.8	
Return Rate (%)	71%	77%	
Number of Subjects in Risk	56	33	
Return Rate in Risk (%)	84%	91%	
Change in SF3602-General Health: NBS at Week 16 from Baseline			
n	36	26	
Mean (SD)	0.7 (5.96)	-0.5 (7.78)	
Median	0.0	-0.5	
Q1, Q3	-4.0, 5.7	-4.8, 4.8	
Min, Max	-9.5, 19.0	-16.6, 15.2	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.60 [1.13] (-1.65, 2.85)		-0.65 [1.26] (-3.16, 1.86)
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.25 [1.68] (-2.10, 4.60)		
MMRM: P-value	0.46		
Corrected Hedges' g (95% CI)	0.187 (-0.319, 0.692)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.42		
Percent Change in SF3602-General Health: NBS at Week 16 from Baseline			
n	36	26	
Mean (SD)	2.8 (17.24)	0.5 (21.50)	
Median	0.0	-0.9	
Q1, Q3	-9.0, 15.4	-13.3, 14.3	
Min, Max	-23.7, 53.4	-41.2, 45.8	
Difference in Percent Change from Baseline at Week 16			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	3.23 [3.14] (-3.04, 9.49)		0.26 [3.51] (-6.74, 7.27)
MMRM: Least Squares Mean Difference [SE] (95% CI)	2.97 [4.68] (-6.38, 12.31)		
MMRM: P-value	0.53		
Corrected Hedges' g (95% CI)	0.159 (-0.346, 0.664)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.53		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
SF3602-General Health: NBS at Week 20		
n	38	29
Mean (SD)	40.2 (8.81)	37.5 (8.54)
Median	39.6	38.0
Q1, Q3	34.2, 46.1	33.2, 42.7
Min, Max	26.1, 65.1	21.3, 57.9
Return Rate (%)	58%	74%
Number of Subjects in Risk	51	32
Return Rate in Risk (%)	75%	91%
Change in SF3602-General Health: NBS at Week 20 from Baseline		
n	30	24
Mean (SD)	0.7 (8.61)	-0.1 (6.96)
Median	0.0	0.0
Q1, Q3	-2.4, 5.7	-4.0, 4.8
Min, Max	-19.0, 15.2	-15.2, 12.8
Difference in Change from Baseline at Week 20		
n [1]	46	27
n [2]	30	24
MMRM: Least Squares Mean [SE] (95% CI)	0.35 [1.22] (-2.09, 2.80)	0.02 [1.35] (-2.68, 2.72)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.33 [1.81] (-3.29, 3.95)	
MMRM: P-value	0.85	
Corrected Hedges' g (95% CI)	0.050 (-0.487, 0.586)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.12	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in SF3602-General Health: NBS at Week 20 from Baseline		
n	30	24
Mean (SD)	4.8 (21.92)	2.5 (19.23)
Median	0.0	0.0
Q1, Q3	-8.4, 15.4	-9.2, 14.9
Min, Max	-35.8, 45.6	-35.4, 40.1
Difference in Percent Change from Baseline at Week 20		
n [1]	46	27
n [2]	30	24
MMRM: Least Squares Mean [SE] (95% CI)	4.22 [3.20] (-2.18, 10.61)	2.93 [3.48] (-4.03, 9.88)
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.29 [4.71] (-8.11, 10.69)	
MMRM: P-value	0.78	
Corrected Hedges' g (95% CI)	0.073 (-0.464, 0.610)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.11	
SF3602-General Health: NBS at Week 24		
n	37	29
Mean (SD)	40.2 (11.40)	35.1 (8.04)
Median	35.6	35.6
Q1, Q3	33.2, 48.4	28.5, 40.4
Min, Max	19.0, 65.1	21.3, 53.2
Return Rate (%)	56%	74%
Number of Subjects in Risk	48	31
Return Rate in Risk (%)	77%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in SF3602-General Health: NBS at Week 24 from Baseline			
n	26	23	
Mean (SD)	1.4 (7.57)	-2.2 (7.40)	
Median	0.0	0.0	
Q1, Q3	-4.8, 4.8	-7.1, 2.4	
Min, Max	-9.5, 24.7	-19.0, 8.1	
Difference in Change from Baseline at Week 24			
n [1]	46	27	
n [2]	26	23	
MMRM: Least Squares Mean [SE] (95% CI)	1.12 [1.32] (-1.51, 3.75)	-2.03 [1.44] (-4.90, 0.85)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	3.14 [1.95] (-0.74, 7.03)		
MMRM: P-value	0.11		
Corrected Hedges' g (95% CI)	0.454 (-0.114, 1.022)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.14		
Percent Change in SF3602-General Health: NBS at Week 24 from Baseline			
n	26	23	
Mean (SD)	4.4 (21.05)	-3.2 (20.29)	
Median	0.0	0.0	
Q1, Q3	-8.4, 14.3	-17.5, 9.1	
Min, Max	-25.0, 69.5	-47.1, 37.6	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	46	27	
n [2]	26	23	
MMRM: Least Squares Mean [SE] (95% CI)	4.30 [3.71] (-3.12, 11.71)		-2.86 [3.97] (-10.78, 5.07)
MMRM: Least Squares Mean Difference [SE] (95% CI)	7.15 [5.41] (-3.65, 17.96)		
MMRM: P-value	0.19		
Corrected Hedges' g (95% CI)	0.371 (-0.195, 0.937)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.20		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
SF3602-Vitality: NBS at Baseline		
n	50	29
Mean (SD)	43.2 (10.49)	39.8 (10.20)
Median	43.7	40.7
Q1, Q3	34.8, 49.6	31.8, 46.7
Min, Max	25.9, 70.4	22.9, 55.6
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
SF3602-Vitality: NBS at Week 4		
n	57	31
Mean (SD)	43.5 (10.24)	40.0 (8.67)
Median	43.7	40.7
Q1, Q3	34.8, 49.6	34.8, 46.7
Min, Max	25.9, 70.4	22.9, 58.5
Return Rate (%)	86%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	86%	84%
Change in SF3602-Vitality: NBS at Week 4 from Baseline		
n	44	26
Mean (SD)	-0.5 (9.00)	0.1 (6.69)
Median	0.0	-1.5
Q1, Q3	-5.9, 4.5	-5.9, 5.9
Min, Max	-29.7, 14.9	-11.9, 14.9

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	46	27	
n [2]	44	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.09 [1.23] (-2.35, 2.54)		-0.63 [1.48] (-3.58, 2.32)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.72 [1.92] (-3.11, 4.55)		
MMRM: P-value	0.71		
Corrected Hedges' g (95% CI)	0.090 (-0.395, 0.575)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.90		
Percent Change in SF3602-Vitality: NBS at Week 4 from Baseline			
n	44	26	
Mean (SD)	0.8 (20.98)	3.0 (20.19)	
Median	0.0	-2.8	
Q1, Q3	-11.6, 11.7	-12.7, 13.6	
Min, Max	-42.2, 57.5	-21.4, 57.5	
Difference in Percent Change from Baseline at Week 4			
n [1]	46	27	
n [2]	44	26	
MMRM: Least Squares Mean [SE] (95% CI)	3.29 [3.02] (-2.73, 9.30)		0.94 [3.65] (-6.34, 8.22)
MMRM: Least Squares Mean Difference [SE] (95% CI)	2.34 [4.73] (-7.09, 11.78)		
MMRM: P-value	0.62		
Corrected Hedges' g (95% CI)	0.119 (-0.366, 0.604)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.79		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
SF3602-Vitality: NBS at Week 8			
n	56	27	
Mean (SD)	42.7 (10.91)	42.5 (10.37)	
Median	40.7	43.7	
Q1, Q3	34.8, 51.1	34.8, 49.6	
Min, Max	22.9, 64.5	22.9, 61.5	
Return Rate (%)	85%	69%	
Number of Subjects in Risk	61	36	
Return Rate in Risk (%)	92%	75%	
Change in SF3602-Vitality: NBS at Week 8 from Baseline			
n	44	24	
Mean (SD)	-0.9 (8.30)	1.4 (6.95)	
Median	-3.0	3.0	
Q1, Q3	-5.9, 7.4	-3.0, 3.0	
Min, Max	-20.8, 14.9	-11.9, 23.8	
Difference in Change from Baseline at Week 8			
n [1]	46	27	
n [2]	44	24	
MMRM: Least Squares Mean [SE] (95% CI)	-0.83 [1.28] (-3.38, 1.72)	1.26 [1.58] (-1.90, 4.42)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.09 [2.02] (-6.13, 1.94)		
MMRM: P-value	0.30		
Corrected Hedges' g (95% CI)	-0.251 (-0.751, 0.248)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.39		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in SF3602-Vitality: NBS at Week 8 from Baseline			
n	44	24	
Mean (SD)	-0.7 (21.93)	5.1 (21.70)	
Median	-5.6	6.6	
Q1, Q3	-18.0, 17.5	-7.1, 8.9	
Min, Max	-44.6, 57.5	-24.0, 91.9	
Difference in Percent Change from Baseline at Week 8			
n [1]	46	27	
n [2]	44	24	
MMRM: Least Squares Mean [SE] (95% CI)	0.69 [3.44] (-6.17, 7.55)	4.52 [4.31] (-4.08, 13.12)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-3.83 [5.49] (-14.79, 7.13)		
MMRM: P-value	0.49		
Corrected Hedges' g (95% CI)	-0.170 (-0.669, 0.328)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.30		
SF3602-Vitality: NBS at Week 12			
n	49	30	
Mean (SD)	43.6 (11.12)	41.1 (10.40)	
Median	43.7	42.2	
Q1, Q3	34.8, 49.6	31.8, 49.6	
Min, Max	22.9, 67.5	22.9, 58.5	
Return Rate (%)	74%	77%	
Number of Subjects in Risk	59	33	
Return Rate in Risk (%)	83%	91%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in SF3602-Vitality: NBS at Week 12 from Baseline		
n	36	26
Mean (SD)	-1.0 (11.03)	-0.2 (8.19)
Median	0.0	1.5
Q1, Q3	-8.9, 7.4	-5.9, 3.0
Min, Max	-26.7, 20.8	-14.9, 20.8
Difference in Change from Baseline at Week 12		
n [1]	46	27
n [2]	36	26
MMRM: Least Squares Mean [SE] (95% CI)	-1.28 [1.57] (-4.41, 1.86)	-0.58 [1.87] (-4.32, 3.15)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.69 [2.44] (-5.56, 4.17)	
MMRM: P-value	0.78	
Corrected Hedges' g (95% CI)	-0.072 (-0.577, 0.433)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.87	
Percent Change in SF3602-Vitality: NBS at Week 12 from Baseline		
n	36	26
Mean (SD)	0.5 (27.69)	1.3 (23.38)
Median	0.0	3.0
Q1, Q3	-20.3, 18.3	-16.0, 13.0
Min, Max	-53.9, 80.4	-39.3, 80.4

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 12			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.72 [3.95] (-7.17, 8.61)		0.35 [4.73] (-9.08, 9.79)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.36 [6.15] (-11.92, 12.64)		
MMRM: P-value	0.95		
Corrected Hedges' g (95% CI)	0.015 (-0.489, 0.519)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.83		
SF3602-Vitality: NBS at Week 16			
n	47	30	
Mean (SD)	43.7 (10.15)	40.7 (10.26)	
Median	43.7	42.2	
Q1, Q3	34.8, 49.6	31.8, 49.6	
Min, Max	22.9, 67.5	22.9, 58.5	
Return Rate (%)	71%	77%	
Number of Subjects in Risk	56	33	
Return Rate in Risk (%)	84%	91%	
Change in SF3602-Vitality: NBS at Week 16 from Baseline			
n	36	26	
Mean (SD)	0.5 (8.33)	-0.5 (8.18)	
Median	3.0	0.0	
Q1, Q3	-5.9, 5.9	-3.0, 5.9	
Min, Max	-14.9, 14.9	-17.8, 17.8	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.56 [1.38] (-3.32, 2.19)	-0.81 [1.60] (-4.00, 2.38)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.25 [2.11] (-3.95, 4.45)		
MMRM: P-value	0.91		
Corrected Hedges' g (95% CI)	0.030 (-0.475, 0.534)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.26		
Percent Change in SF3602-Vitality: NBS at Week 16 from Baseline			
n	36	26	
Mean (SD)	3.2 (20.36)	0.9 (23.08)	
Median	6.6	0.0	
Q1, Q3	-11.6, 18.0	-10.3, 12.0	
Min, Max	-34.2, 45.9	-38.2, 68.9	
Difference in Percent Change from Baseline at Week 16			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	2.23 [3.38] (-4.53, 8.98)	-0.10 [3.91] (-7.90, 7.70)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	2.33 [5.15] (-7.96, 12.61)		
MMRM: P-value	0.65		
Corrected Hedges' g (95% CI)	0.114 (-0.391, 0.619)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.25		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
SF3602-Vitality: NBS at Week 20			
n	38	29	
Mean (SD)	46.3 (10.40)	43.0 (10.67)	
Median	46.7	43.7	
Q1, Q3	37.7, 55.6	37.7, 49.6	
Min, Max	28.8, 70.4	22.9, 67.5	
Return Rate (%)	58%	74%	
Number of Subjects in Risk	51	32	
Return Rate in Risk (%)	75%	91%	
Change in SF3602-Vitality: NBS at Week 20 from Baseline			
n	30	24	
Mean (SD)	1.8 (8.46)	3.1 (6.93)	
Median	3.0	3.0	
Q1, Q3	-5.9, 8.9	-1.5, 5.9	
Min, Max	-11.9, 20.8	-8.9, 23.8	
Difference in Change from Baseline at Week 20			
n [1]	46	27	
n [2]	30	24	
MMRM: Least Squares Mean [SE] (95% CI)	1.73 [1.39] (-1.04, 4.49)	2.24 [1.55] (-0.84, 5.33)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.52 [2.07] (-4.65, 3.61)		
MMRM: P-value	0.80		
Corrected Hedges' g (95% CI)	-0.067 (-0.604, 0.469)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.79		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in SF3602-Vitality: NBS at Week 20 from Baseline		
n	30	24
Mean (SD)	6.0 (20.54)	9.2 (19.85)
Median	6.0	6.6
Q1, Q3	-11.3, 23.0	-3.2, 14.2
Min, Max	-24.0, 51.1	-28.0, 57.5
Difference in Percent Change from Baseline at Week 20		
n [1]	46	27
n [2]	30	24
MMRM: Least Squares Mean [SE] (95% CI)	7.29 [3.42] (0.46, 14.12)	7.10 [3.82] (-0.53, 14.72)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.19 [5.11] (-10.01, 10.39)	
MMRM: P-value	0.97	
Corrected Hedges' g (95% CI)	0.010 (-0.527, 0.547)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.91	
SF3602-Vitality: NBS at Week 24		
n	37	29
Mean (SD)	44.6 (11.05)	40.7 (12.15)
Median	43.7	40.7
Q1, Q3	37.7, 52.6	28.8, 52.6
Min, Max	25.9, 67.5	22.9, 64.5
Return Rate (%)	56%	74%
Number of Subjects in Risk	48	31
Return Rate in Risk (%)	77%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in SF3602-Vitality: NBS at Week 24 from Baseline			
n	26	23	
Mean (SD)	-0.3 (8.62)	0.8 (6.89)	
Median	0.0	0.0	
Q1, Q3	-3.0, 5.9	-3.0, 5.9	
Min, Max	-20.8, 14.9	-14.9, 20.8	
Difference in Change from Baseline at Week 24			
n [1]	46	27	
n [2]	26	23	
MMRM: Least Squares Mean [SE] (95% CI)	-0.23 [1.48] (-3.17, 2.72)	-0.13 [1.60] (-3.33, 3.08)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.10 [2.17] (-4.44, 4.24)		
MMRM: P-value	0.96		
Corrected Hedges' g (95% CI)	-0.013 (-0.574, 0.548)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.47		
Percent Change in SF3602-Vitality: NBS at Week 24 from Baseline			
n	26	23	
Mean (SD)	1.8 (20.41)	1.9 (18.02)	
Median	0.0	0.0	
Q1, Q3	-9.3, 11.5	-9.3, 12.0	
Min, Max	-44.6, 45.9	-36.5, 47.6	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	46	27	
n [2]	26	23	
MMRM: Least Squares Mean [SE] (95% CI)	3.72 [3.56] (-3.40, 10.83)		-0.16 [3.84] (-7.81, 7.50)
MMRM: Least Squares Mean Difference [SE] (95% CI)	3.88 [5.22] (-6.54, 14.29)		
MMRM: P-value	0.46		
Corrected Hedges' g (95% CI)	0.209 (-0.354, 0.771)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.45		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
SF3602-Social Functioning: NBS at Baseline		
n	50	29
Mean (SD)	42.5 (10.23)	40.4 (10.75)
Median	42.3	37.3
Q1, Q3	32.3, 52.3	37.3, 47.3
Min, Max	27.3, 57.3	17.2, 57.3
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
SF3602-Social Functioning: NBS at Week 4		
n	57	31
Mean (SD)	42.7 (10.50)	40.2 (11.12)
Median	42.3	37.3
Q1, Q3	37.3, 52.3	32.3, 47.3
Min, Max	17.2, 57.3	17.2, 57.3
Return Rate (%)	86%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	86%	84%
Change in SF3602-Social Functioning: NBS at Week 4 from Baseline		
n	44	26
Mean (SD)	-0.2 (9.96)	-0.2 (9.35)
Median	0.0	0.0
Q1, Q3	-5.0, 5.0	-5.0, 5.0
Min, Max	-30.1, 15.0	-20.1, 15.0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	46	27	
n [2]	44	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.61 [1.41] (-2.21, 3.43)		-0.68 [1.73] (-4.13, 2.76)
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.29 [2.22] (-3.15, 5.73)		
MMRM: P-value	0.56		
Corrected Hedges' g (95% CI)	0.139 (-0.346, 0.625)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.94		
Percent Change in SF3602-Social Functioning: NBS at Week 4 from Baseline			
n	44	26	
Mean (SD)	1.8 (23.06)	2.3 (23.95)	
Median	0.0	0.0	
Q1, Q3	-10.7, 14.5	-10.6, 22.5	
Min, Max	-52.5, 55.2	-42.4, 40.3	
Difference in Percent Change from Baseline at Week 4			
n [1]	46	27	
n [2]	44	26	
MMRM: Least Squares Mean [SE] (95% CI)	3.96 [3.42] (-2.87, 10.79)		0.82 [4.15] (-7.47, 9.11)
MMRM: Least Squares Mean Difference [SE] (95% CI)	3.14 [5.36] (-7.57, 13.85)		
MMRM: P-value	0.56		
Corrected Hedges' g (95% CI)	0.140 (-0.345, 0.626)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.97		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
SF3602-Social Functioning: NBS at Week 8			
n	56	27	
Mean (SD)	44.0 (10.48)	42.9 (11.49)	
Median	47.3	42.3	
Q1, Q3	37.3, 52.3	37.3, 52.3	
Min, Max	17.2, 57.3	17.2, 57.3	
Return Rate (%)	85%	69%	
Number of Subjects in Risk	61	36	
Return Rate in Risk (%)	92%	75%	
Change in SF3602-Social Functioning: NBS at Week 8 from Baseline			
n	44	24	
Mean (SD)	0.9 (7.19)	0.2 (11.78)	
Median	0.0	0.0	
Q1, Q3	-5.0, 5.0	-7.5, 7.5	
Min, Max	-20.1, 15.0	-25.1, 30.1	
Difference in Change from Baseline at Week 8			
n [1]	46	27	
n [2]	44	24	
MMRM: Least Squares Mean [SE] (95% CI)	1.07 [1.35] (-1.63, 3.77)	0.40 [1.67] (-2.93, 3.73)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.67 [2.14] (-3.59, 4.93)		
MMRM: P-value	0.75		
Corrected Hedges' g (95% CI)	0.076 (-0.422, 0.574)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.36		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in SF3602-Social Functioning: NBS at Week 8 from Baseline		
n	44	24
Mean (SD)	3.6 (18.41)	6.7 (44.40)
Median	0.0	0.0
Q1, Q3	-8.7, 15.6	-15.9, 18.4
Min, Max	-46.6, 40.3	-53.0, 174.6
Difference in Percent Change from Baseline at Week 8		
n [1]	46	27
n [2]	44	24
MMRM: Least Squares Mean [SE] (95% CI)	4.58 [4.22] (-3.83, 13.00)	7.17 [5.37] (-3.54, 17.88)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.59 [6.80] (-16.16, 10.98)	
MMRM: P-value	0.70	
Corrected Hedges' g (95% CI)	-0.093 (-0.591, 0.404)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.31	
SF3602-Social Functioning: NBS at Week 12		
n	49	30
Mean (SD)	43.5 (10.81)	40.5 (11.29)
Median	42.3	42.3
Q1, Q3	37.3, 52.3	32.3, 47.3
Min, Max	17.2, 57.3	17.2, 57.3
Return Rate (%)	74%	77%
Number of Subjects in Risk	59	33
Return Rate in Risk (%)	83%	91%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in SF3602-Social Functioning: NBS at Week 12 from Baseline			
n	36	26	
Mean (SD)	0.1 (8.26)	-1.9 (9.31)	
Median	0.0	0.0	
Q1, Q3	-5.0, 5.0	-10.0, 5.0	
Min, Max	-15.0, 20.1	-25.1, 15.0	
Difference in Change from Baseline at Week 12			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.66 [1.43] (-2.19, 3.51)	-1.95 [1.65] (-5.23, 1.34)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	2.61 [2.17] (-1.72, 6.93)		
MMRM: P-value	0.23		
Corrected Hedges' g (95% CI)	0.303 (-0.204, 0.810)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.28		
Percent Change in SF3602-Social Functioning: NBS at Week 12 from Baseline			
n	36	26	
Mean (SD)	1.9 (20.63)	-2.1 (25.29)	
Median	0.0	0.0	
Q1, Q3	-10.1, 18.4	-17.5, 13.4	
Min, Max	-46.6, 53.8	-53.0, 58.2	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 12			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	4.26 [3.70] (-3.14, 11.65)		-2.08 [4.26] (-10.59, 6.42)
MMRM: Least Squares Mean Difference [SE] (95% CI)	6.34 [5.62] (-4.87, 17.55)		
MMRM: P-value	0.26		
Corrected Hedges' g (95% CI)	0.284 (-0.223, 0.791)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.22		
SF3602-Social Functioning: NBS at Week 16			
n	47	30	
Mean (SD)	42.5 (10.40)	41.8 (10.14)	
Median	42.3	42.3	
Q1, Q3	37.3, 52.3	37.3, 47.3	
Min, Max	17.2, 57.3	22.3, 57.3	
Return Rate (%)	71%	77%	
Number of Subjects in Risk	56	33	
Return Rate in Risk (%)	84%	91%	
Change in SF3602-Social Functioning: NBS at Week 16 from Baseline			
n	36	26	
Mean (SD)	-0.3 (9.73)	-1.4 (8.57)	
Median	0.0	0.0	
Q1, Q3	-5.0, 5.0	-5.0, 5.0	
Min, Max	-25.1, 25.1	-20.1, 10.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.04 [1.41] (-2.84, 2.77)	-1.37 [1.56] (-4.49, 1.75)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.33 [2.09] (-2.84, 5.50)		
MMRM: P-value	0.53		
Corrected Hedges' g (95% CI)	0.159 (-0.346, 0.664)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.37		
Percent Change in SF3602-Social Functioning: NBS at Week 16 from Baseline			
n	36	26	
Mean (SD)	2.4 (26.12)	-0.3 (21.58)	
Median	0.0	0.0	
Q1, Q3	-13.5, 12.6	-17.5, 13.4	
Min, Max	-46.6, 77.7	-35.0, 45.0	
Difference in Percent Change from Baseline at Week 16			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	3.16 [3.66] (-4.14, 10.46)	-0.34 [4.08] (-8.49, 7.80)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	3.50 [5.45] (-7.37, 14.38)		
MMRM: P-value	0.52		
Corrected Hedges' g (95% CI)	0.161 (-0.344, 0.666)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.41		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
SF3602-Social Functioning: NBS at Week 20		
n	38	29
Mean (SD)	45.2 (10.14)	43.0 (10.94)
Median	47.3	42.3
Q1, Q3	42.3, 52.3	37.3, 47.3
Min, Max	22.3, 57.3	22.3, 57.3
Return Rate (%)	58%	74%
Number of Subjects in Risk	51	32
Return Rate in Risk (%)	75%	91%
Change in SF3602-Social Functioning: NBS at Week 20 from Baseline		
n	30	24
Mean (SD)	2.7 (8.61)	0.6 (9.39)
Median	2.5	0.0
Q1, Q3	0.0, 5.0	-5.0, 7.5
Min, Max	-15.0, 30.1	-25.1, 20.1
Difference in Change from Baseline at Week 20		
n [1]	46	27
n [2]	30	24
MMRM: Least Squares Mean [SE] (95% CI)	2.88 [1.43] (0.03, 5.73)	0.64 [1.54] (-2.43, 3.70)
MMRM: Least Squares Mean Difference [SE] (95% CI)	2.24 [2.08] (-1.92, 6.41)	
MMRM: P-value	0.29	
Corrected Hedges' g (95% CI)	0.288 (-0.252, 0.827)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.12	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in SF3602-Social Functioning: NBS at Week 20 from Baseline		
n	30	24
Mean (SD)	9.9 (25.85)	4.6 (24.93)
Median	5.3	0.0
Q1, Q3	0.0, 18.4	-9.2, 21.9
Min, Max	-31.8, 110.3	-53.0, 58.2
Difference in Percent Change from Baseline at Week 20		
n [1]	46	27
n [2]	30	24
MMRM: Least Squares Mean [SE] (95% CI)	10.01 [3.88] (2.26, 17.76)	4.41 [4.22] (-4.02, 12.84)
MMRM: Least Squares Mean Difference [SE] (95% CI)	5.60 [5.71] (-5.79, 16.99)	
MMRM: P-value	0.33	
Corrected Hedges' g (95% CI)	0.263 (-0.276, 0.802)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.13	
SF3602-Social Functioning: NBS at Week 24		
n	37	29
Mean (SD)	45.4 (9.26)	40.9 (11.98)
Median	47.3	42.3
Q1, Q3	37.3, 52.3	37.3, 52.3
Min, Max	27.3, 57.3	17.2, 57.3
Return Rate (%)	56%	74%
Number of Subjects in Risk	48	31
Return Rate in Risk (%)	77%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in SF3602-Social Functioning: NBS at Week 24 from Baseline			
n	26	23	
Mean (SD)	2.1 (9.10)	0.2 (8.61)	
Median	0.0	0.0	
Q1, Q3	0.0, 5.0	-5.0, 5.0	
Min, Max	-20.1, 20.1	-20.1, 15.0	
Difference in Change from Baseline at Week 24			
n [1]	46	27	
n [2]	26	23	
MMRM: Least Squares Mean [SE] (95% CI)	3.06 [1.59] (-0.11, 6.23)	-0.37 [1.66] (-3.69, 2.94)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	3.43 [2.29] (-1.13, 8.00)		
MMRM: P-value	0.14		
Corrected Hedges' g (95% CI)	0.421 (-0.147, 0.988)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.35		
Percent Change in SF3602-Social Functioning: NBS at Week 24 from Baseline			
n	26	23	
Mean (SD)	8.4 (26.44)	3.1 (27.04)	
Median	0.0	0.0	
Q1, Q3	0.0, 13.4	-10.6, 15.6	
Min, Max	-35.0, 73.6	-42.4, 67.6	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	46	27	
n [2]	26	23	
MMRM: Least Squares Mean [SE] (95% CI)	10.70 [4.59] (1.54, 19.86)		1.54 [4.94] (-8.33, 11.41)
MMRM: Least Squares Mean Difference [SE] (95% CI)	9.16 [6.72] (-4.25, 22.57)		
MMRM: P-value	0.18		
Corrected Hedges' g (95% CI)	0.383 (-0.183, 0.949)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.32		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
SF3602-Role Emotional: NBS at Baseline		
n	50	29
Mean (SD)	43.0 (11.94)	42.7 (14.47)
Median	45.7	45.7
Q1, Q3	35.3, 56.2	35.3, 56.2
Min, Max	14.4, 56.2	14.4, 56.2
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
SF3602-Role Emotional: NBS at Week 4		
n	57	31
Mean (SD)	44.9 (11.11)	43.1 (11.82)
Median	49.2	45.7
Q1, Q3	35.3, 56.2	35.3, 52.7
Min, Max	14.4, 56.2	14.4, 56.2
Return Rate (%)	86%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	86%	84%
Change in SF3602-Role Emotional: NBS at Week 4 from Baseline		
n	44	26
Mean (SD)	0.9 (11.20)	0.3 (9.55)
Median	0.0	0.0
Q1, Q3	-3.5, 7.0	-3.5, 7.0
Min, Max	-27.9, 27.9	-27.9, 13.9

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	46	27	
n [2]	44	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.65 [1.46] (-2.28, 3.57)		-0.39 [1.75] (-3.89, 3.10)
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.04 [2.27] (-3.49, 5.57)		
MMRM: P-value	0.65		
Corrected Hedges' g (95% CI)	0.109 (-0.376, 0.594)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.58		
Percent Change in SF3602-Role Emotional: NBS at Week 4 from Baseline			
n	44	26	
Mean (SD)	8.9 (36.81)	6.1 (25.97)	
Median	0.0	0.0	
Q1, Q3	-6.4, 16.5	-6.6, 24.7	
Min, Max	-59.2, 136.4	-49.6, 78.0	
Difference in Percent Change from Baseline at Week 4			
n [1]	46	27	
n [2]	44	26	
MMRM: Least Squares Mean [SE] (95% CI)	8.07 [4.10] (-0.11, 16.24)		4.25 [4.89] (-5.51, 14.02)
MMRM: Least Squares Mean Difference [SE] (95% CI)	3.81 [6.35] (-8.87, 16.49)		
MMRM: P-value	0.55		
Corrected Hedges' g (95% CI)	0.143 (-0.342, 0.628)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.50		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
SF3602-Role Emotional: NBS at Week 8			
n	56	27	
Mean (SD)	43.5 (12.57)	45.6 (11.53)	
Median	45.7	45.7	
Q1, Q3	33.5, 56.2	38.8, 56.2	
Min, Max	14.4, 56.2	14.4, 56.2	
Return Rate (%)	85%	69%	
Number of Subjects in Risk	61	36	
Return Rate in Risk (%)	92%	75%	
Change in SF3602-Role Emotional: NBS at Week 8 from Baseline			
n	44	24	
Mean (SD)	-1.3 (9.08)	0.6 (7.45)	
Median	0.0	0.0	
Q1, Q3	-7.0, 3.5	0.0, 3.5	
Min, Max	-27.9, 13.9	-13.9, 17.4	
Difference in Change from Baseline at Week 8			
n [1]	46	27	
n [2]	44	24	
MMRM: Least Squares Mean [SE] (95% CI)	-1.60 [1.31] (-4.22, 1.03)	0.88 [1.56] (-2.23, 3.98)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.47 [2.02] (-6.50, 1.56)		
MMRM: P-value	0.23		
Corrected Hedges' g (95% CI)	-0.293 (-0.792, 0.207)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.31		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in SF3602-Role Emotional: NBS at Week 8 from Baseline			
n	44	24	
Mean (SD)	-0.7 (25.55)	6.9 (26.24)	
Median	0.0	0.0	
Q1, Q3	-15.2, 8.8	0.0, 9.9	
Min, Max	-59.2, 72.6	-24.8, 97.4	
Difference in Percent Change from Baseline at Week 8			
n [1]	46	27	
n [2]	44	24	
MMRM: Least Squares Mean [SE] (95% CI)	-1.16 [3.74] (-8.62, 6.31)	7.55 [4.45] (-1.32, 16.42)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-8.71 [5.77] (-20.23, 2.81)		
MMRM: P-value	0.14		
Corrected Hedges' g (95% CI)	-0.362 (-0.863, 0.139)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.28		
SF3602-Role Emotional: NBS at Week 12			
n	49	30	
Mean (SD)	45.3 (10.98)	45.3 (11.88)	
Median	45.7	47.5	
Q1, Q3	35.3, 56.2	38.8, 56.2	
Min, Max	24.8, 56.2	14.4, 56.2	
Return Rate (%)	74%	77%	
Number of Subjects in Risk	59	33	
Return Rate in Risk (%)	83%	91%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in SF3602-Role Emotional: NBS at Week 12 from Baseline			
n	36	26	
Mean (SD)	-0.1 (11.64)	0.3 (7.30)	
Median	0.0	0.0	
Q1, Q3	-7.0, 8.7	-3.5, 3.5	
Min, Max	-31.3, 24.4	-17.4, 13.9	
Difference in Change from Baseline at Week 12			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.14 [1.47] (-3.09, 2.80)	0.43 [1.64] (-2.84, 3.71)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.58 [2.19] (-4.95, 3.80)		
MMRM: P-value	0.79		
Corrected Hedges' g (95% CI)	-0.066 (-0.570, 0.439)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.76		
Percent Change in SF3602-Role Emotional: NBS at Week 12 from Baseline			
n	36	26	
Mean (SD)	7.4 (40.35)	5.5 (25.15)	
Median	0.0	0.0	
Q1, Q3	-18.6, 23.8	-7.1, 8.2	
Min, Max	-55.8, 169.4	-31.0, 78.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 12			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	6.84 [4.47] (-2.08, 15.76)	6.13 [5.09] (-4.02, 16.29)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.70 [6.74] (-12.75, 14.16)		
MMRM: P-value	0.92		
Corrected Hedges' g (95% CI)	0.026 (-0.478, 0.531)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.80		
SF3602-Role Emotional: NBS at Week 16			
n	47	30	
Mean (SD)	46.5 (11.04)	44.1 (12.83)	
Median	49.2	45.7	
Q1, Q3	42.2, 56.2	35.3, 56.2	
Min, Max	17.9, 56.2	14.4, 56.2	
Return Rate (%)	71%	77%	
Number of Subjects in Risk	56	33	
Return Rate in Risk (%)	84%	91%	
Change in SF3602-Role Emotional: NBS at Week 16 from Baseline			
n	36	26	
Mean (SD)	1.8 (10.38)	-0.4 (7.39)	
Median	0.0	0.0	
Q1, Q3	-3.5, 7.0	-3.5, 3.5	
Min, Max	-31.3, 20.9	-13.9, 17.4	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	1.37 [1.45] (-1.53, 4.27)		-0.24 [1.62] (-3.46, 2.99)
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.61 [2.16] (-2.70, 5.92)		
MMRM: P-value	0.46		
Corrected Hedges' g (95% CI)	0.186 (-0.319, 0.692)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.20		
Percent Change in SF3602-Role Emotional: NBS at Week 16 from Baseline			
n	36	26	
Mean (SD)	9.8 (35.12)	2.5 (24.21)	
Median	0.0	0.0	
Q1, Q3	-7.1, 18.0	-6.2, 6.6	
Min, Max	-55.8, 145.2	-29.6, 97.4	
Difference in Percent Change from Baseline at Week 16			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	7.96 [4.34] (-0.70, 16.62)		3.09 [4.92] (-6.73, 12.90)
MMRM: Least Squares Mean Difference [SE] (95% CI)	4.87 [6.52] (-8.15, 17.89)		
MMRM: P-value	0.46		
Corrected Hedges' g (95% CI)	0.188 (-0.318, 0.693)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.16		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
SF3602-Role Emotional: NBS at Week 20		
n	38	29
Mean (SD)	47.0 (10.66)	44.2 (12.40)
Median	50.9	45.7
Q1, Q3	42.2, 56.2	31.8, 56.2
Min, Max	14.4, 56.2	17.9, 56.2
Return Rate (%)	58%	74%
Number of Subjects in Risk	51	32
Return Rate in Risk (%)	75%	91%
Change in SF3602-Role Emotional: NBS at Week 20 from Baseline		
n	30	24
Mean (SD)	1.0 (9.06)	-0.7 (7.95)
Median	0.0	0.0
Q1, Q3	-3.5, 7.0	-3.5, 3.5
Min, Max	-20.9, 20.9	-24.4, 13.9
Difference in Change from Baseline at Week 20		
n [1]	46	27
n [2]	30	24
MMRM: Least Squares Mean [SE] (95% CI)	0.50 [1.48] (-2.46, 3.46)	-0.54 [1.58] (-3.70, 2.62)
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.05 [2.16] (-3.26, 5.35)	
MMRM: P-value	0.63	
Corrected Hedges' g (95% CI)	0.129 (-0.408, 0.667)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.62	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in SF3602-Role Emotional: NBS at Week 20 from Baseline		
n	30	24
Mean (SD)	4.2 (23.70)	3.4 (24.51)
Median	0.0	0.0
Q1, Q3	-7.6, 16.5	-11.1, 9.1
Min, Max	-44.9, 59.2	-43.4, 78.0
Difference in Percent Change from Baseline at Week 20		
n [1]	46	27
n [2]	30	24
MMRM: Least Squares Mean [SE] (95% CI)	2.52 [4.27] (-6.01, 11.04)	4.13 [4.68] (-5.22, 13.47)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.61 [6.30] (-14.19, 10.98)	
MMRM: P-value	0.80	
Corrected Hedges' g (95% CI)	-0.068 (-0.605, 0.469)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.94	
SF3602-Role Emotional: NBS at Week 24		
n	37	29
Mean (SD)	46.5 (10.12)	44.5 (12.60)
Median	49.2	49.2
Q1, Q3	42.2, 56.2	35.3, 56.2
Min, Max	24.8, 56.2	14.4, 56.2
Return Rate (%)	56%	74%
Number of Subjects in Risk	48	31
Return Rate in Risk (%)	77%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in SF3602-Role Emotional: NBS at Week 24 from Baseline			
n	26	23	
Mean (SD)	-0.9 (9.32)	-0.3 (12.15)	
Median	0.0	0.0	
Q1, Q3	-7.0, 3.5	-3.5, 7.0	
Min, Max	-24.4, 20.9	-41.8, 17.4	
Difference in Change from Baseline at Week 24			
n [1]	46	27	
n [2]	26	23	
MMRM: Least Squares Mean [SE] (95% CI)	-0.98 [1.83] (-4.63, 2.68)	-0.60 [1.97] (-4.54, 3.34)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.38 [2.68] (-5.73, 4.97)		
MMRM: P-value	0.89		
Corrected Hedges' g (95% CI)	-0.040 (-0.601, 0.521)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.97		
Percent Change in SF3602-Role Emotional: NBS at Week 24 from Baseline			
n	26	23	
Mean (SD)	-0.2 (22.62)	6.1 (31.85)	
Median	0.0	0.0	
Q1, Q3	-12.4, 9.0	-6.2, 24.7	
Min, Max	-43.4, 59.2	-74.4, 97.4	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	46	27	
n [2]	26	23	
MMRM: Least Squares Mean [SE] (95% CI)	1.50 [4.80] (-8.09, 11.08)		5.03 [5.21] (-5.37, 15.43)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-3.54 [7.06] (-17.62, 10.55)		
MMRM: P-value	0.62		
Corrected Hedges' g (95% CI)	-0.141 (-0.702, 0.421)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.71		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
SF3602-Mental Health: NBS at Baseline		
n	50	29
Mean (SD)	47.2 (9.85)	45.1 (11.54)
Median	46.9	48.3
Q1, Q3	40.4, 56.1	37.8, 53.5
Min, Max	22.1, 64.0	22.1, 58.7
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
SF3602-Mental Health: NBS at Week 4		
n	57	31
Mean (SD)	47.2 (10.61)	47.3 (10.58)
Median	50.9	50.9
Q1, Q3	43.0, 56.1	40.4, 53.5
Min, Max	22.1, 64.0	11.6, 64.0
Return Rate (%)	86%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	86%	84%
Change in SF3602-Mental Health: NBS at Week 4 from Baseline		
n	44	26
Mean (SD)	0.3 (10.16)	2.5 (9.52)
Median	0.0	2.6
Q1, Q3	-5.2, 6.5	0.0, 5.2
Min, Max	-23.5, 20.9	-18.3, 31.4

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	46	27	
n [2]	44	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.53 [1.45] (-2.37, 3.43)		1.86 [1.74] (-1.61, 5.33)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.33 [2.26] (-5.83, 3.17)		
MMRM: P-value	0.56		
Corrected Hedges' g (95% CI)	-0.141 (-0.626, 0.345)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.12		
Percent Change in SF3602-Mental Health: NBS at Week 4 from Baseline			
n	44	26	
Mean (SD)	2.8 (23.83)	9.7 (34.04)	
Median	0.0	7.6	
Q1, Q3	-12.1, 17.3	0.0, 11.5	
Min, Max	-48.8, 56.2	-52.9, 142.1	
Difference in Percent Change from Baseline at Week 4			
n [1]	46	27	
n [2]	44	26	
MMRM: Least Squares Mean [SE] (95% CI)	4.27 [4.03] (-3.78, 12.32)		8.32 [4.88] (-1.42, 18.05)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-4.04 [6.30] (-16.62, 8.53)		
MMRM: P-value	0.52		
Corrected Hedges' g (95% CI)	-0.153 (-0.639, 0.332)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.10		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
SF3602-Mental Health: NBS at Week 8			
n	56	27	
Mean (SD)	46.3 (11.04)	48.1 (10.49)	
Median	46.9	50.9	
Q1, Q3	37.8, 56.1	43.0, 53.5	
Min, Max	11.6, 64.0	11.6, 64.0	
Return Rate (%)	85%	69%	
Number of Subjects in Risk	61	36	
Return Rate in Risk (%)	92%	75%	
Change in SF3602-Mental Health: NBS at Week 8 from Baseline			
n	44	24	
Mean (SD)	-0.9 (9.13)	2.8 (9.69)	
Median	0.0	2.6	
Q1, Q3	-5.2, 5.2	-1.3, 7.8	
Min, Max	-26.2, 23.5	-18.3, 26.2	
Difference in Change from Baseline at Week 8			
n [1]	46	27	
n [2]	44	24	
MMRM: Least Squares Mean [SE] (95% CI)	-0.89 [1.44] (-3.77, 1.99)	2.85 [1.74] (-0.63, 6.33)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-3.74 [2.25] (-8.23, 0.75)		
MMRM: P-value	0.10		
Corrected Hedges' g (95% CI)	-0.401 (-0.903, 0.101)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.37		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in SF3602-Mental Health: NBS at Week 8 from Baseline		
n	44	24
Mean (SD)	-0.8 (21.40)	10.8 (33.15)
Median	0.0	5.1
Q1, Q3	-11.8, 12.4	-2.4, 17.2
Min, Max	-69.2, 62.3	-52.9, 118.4
Difference in Percent Change from Baseline at Week 8		
n [1]	46	27
n [2]	44	24
MMRM: Least Squares Mean [SE] (95% CI)	0.21 [3.89] (-7.55, 7.97)	10.52 [4.71] (1.11, 19.93)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-10.31 [6.07] (-22.43, 1.81)	
MMRM: P-value	0.094	
Corrected Hedges' g (95% CI)	-0.410 (-0.912, 0.092)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.53	
SF3602-Mental Health: NBS at Week 12		
n	49	30
Mean (SD)	46.8 (12.05)	46.3 (10.80)
Median	48.3	50.9
Q1, Q3	37.8, 56.1	40.4, 53.5
Min, Max	22.1, 64.0	11.6, 58.7
Return Rate (%)	74%	77%
Number of Subjects in Risk	59	33
Return Rate in Risk (%)	83%	91%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in SF3602-Mental Health: NBS at Week 12 from Baseline			
n	36	26	
Mean (SD)	-1.8 (10.42)	0.2 (8.81)	
Median	0.0	0.0	
Q1, Q3	-10.5, 5.2	-5.2, 5.2	
Min, Max	-23.5, 23.5	-18.3, 18.3	
Difference in Change from Baseline at Week 12			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	-1.82 [1.54] (-4.88, 1.25)	-0.01 [1.77] (-3.54, 3.52)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.81 [2.33] (-6.45, 2.84)		
MMRM: P-value	0.44		
Corrected Hedges' g (95% CI)	-0.195 (-0.701, 0.310)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.61		
Percent Change in SF3602-Mental Health: NBS at Week 12 from Baseline			
n	36	26	
Mean (SD)	-2.0 (25.06)	4.0 (28.44)	
Median	0.0	0.0	
Q1, Q3	-19.2, 11.1	-9.3, 10.8	
Min, Max	-48.8, 62.3	-52.9, 82.9	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 12			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.90 [4.03] (-8.95, 7.15)		3.64 [4.66] (-5.67, 12.94)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-4.54 [6.12] (-16.76, 7.69)		
MMRM: P-value	0.46		
Corrected Hedges' g (95% CI)	-0.186 (-0.692, 0.319)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.62		
SF3602-Mental Health: NBS at Week 16			
n	47	30	
Mean (SD)	47.1 (11.70)	46.5 (13.15)	
Median	50.9	50.9	
Q1, Q3	40.4, 56.1	37.8, 56.1	
Min, Max	19.5, 64.0	11.6, 64.0	
Return Rate (%)	71%	77%	
Number of Subjects in Risk	56	33	
Return Rate in Risk (%)	84%	91%	
Change in SF3602-Mental Health: NBS at Week 16 from Baseline			
n	36	26	
Mean (SD)	-1.2 (9.62)	-0.5 (9.33)	
Median	0.0	2.6	
Q1, Q3	-10.5, 5.2	-2.6, 5.2	
Min, Max	-20.9, 20.9	-28.8, 13.1	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	-1.13 [1.64] (-4.40, 2.15)	-0.71 [1.87] (-4.45, 3.03)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.41 [2.48] (-5.36, 4.53)		
MMRM: P-value	0.87		
Corrected Hedges' g (95% CI)	-0.042 (-0.546, 0.463)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.74		
Percent Change in SF3602-Mental Health: NBS at Week 16 from Baseline			
n	36	26	
Mean (SD)	-1.7 (21.73)	0.0 (22.83)	
Median	0.0	5.3	
Q1, Q3	-19.6, 11.8	-4.7, 10.3	
Min, Max	-48.7, 55.4	-52.9, 43.7	
Difference in Percent Change from Baseline at Week 16			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.70 [3.96] (-8.62, 7.21)	-0.38 [4.40] (-9.16, 8.39)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.32 [5.87] (-12.05, 11.40)		
MMRM: P-value	0.96		
Corrected Hedges' g (95% CI)	-0.014 (-0.518, 0.491)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.82		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
SF3602-Mental Health: NBS at Week 20		
n	38	29
Mean (SD)	48.4 (10.76)	47.4 (11.62)
Median	46.9	50.9
Q1, Q3	40.4, 58.7	40.4, 53.5
Min, Max	24.7, 64.0	16.9, 64.0
Return Rate (%)	58%	74%
Number of Subjects in Risk	51	32
Return Rate in Risk (%)	75%	91%
Change in SF3602-Mental Health: NBS at Week 20 from Baseline		
n	30	24
Mean (SD)	-0.6 (8.21)	1.4 (9.57)
Median	0.0	2.6
Q1, Q3	-5.2, 5.2	-3.9, 6.5
Min, Max	-15.7, 20.9	-26.2, 23.6
Difference in Change from Baseline at Week 20		
n [1]	46	27
n [2]	30	24
MMRM: Least Squares Mean [SE] (95% CI)	-0.18 [1.53] (-3.25, 2.88)	0.78 [1.70] (-2.61, 4.17)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.96 [2.27] (-5.50, 3.57)	
MMRM: P-value	0.67	
Corrected Hedges' g (95% CI)	-0.114 (-0.651, 0.424)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.56	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in SF3602-Mental Health: NBS at Week 20 from Baseline		
n	30	24
Mean (SD)	-0.7 (17.82)	6.6 (28.43)
Median	0.0	7.2
Q1, Q3	-15.4, 10.8	-6.9, 13.6
Min, Max	-30.9, 55.4	-48.9, 106.6
Difference in Percent Change from Baseline at Week 20		
n [1]	46	27
n [2]	30	24
MMRM: Least Squares Mean [SE] (95% CI)	1.52 [3.79] (-6.04, 9.08)	5.19 [4.17] (-3.13, 13.51)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-3.67 [5.59] (-14.84, 7.49)	
MMRM: P-value	0.51	
Corrected Hedges' g (95% CI)	-0.176 (-0.713, 0.362)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.51	
SF3602-Mental Health: NBS at Week 24		
n	37	29
Mean (SD)	48.5 (10.06)	45.9 (12.40)
Median	48.3	48.3
Q1, Q3	40.4, 58.7	37.8, 56.1
Min, Max	24.7, 64.0	11.6, 64.0
Return Rate (%)	56%	74%
Number of Subjects in Risk	48	31
Return Rate in Risk (%)	77%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in SF3602-Mental Health: NBS at Week 24 from Baseline			
n	26	23	
Mean (SD)	0.0 (7.97)	0.1 (9.11)	
Median	0.0	2.6	
Q1, Q3	-2.6, 2.6	-5.2, 5.2	
Min, Max	-13.1, 20.9	-23.5, 15.7	
Difference in Change from Baseline at Week 24			
n [1]	46	27	
n [2]	26	23	
MMRM: Least Squares Mean [SE] (95% CI)	-0.02 [1.51] (-3.05, 3.00)	-0.32 [1.58] (-3.48, 2.84)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.30 [2.18] (-4.05, 4.65)		
MMRM: P-value	0.89		
Corrected Hedges' g (95% CI)	0.038 (-0.523, 0.599)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.61		
Percent Change in SF3602-Mental Health: NBS at Week 24 from Baseline			
n	26	23	
Mean (SD)	1.2 (18.54)	2.9 (26.15)	
Median	0.0	5.4	
Q1, Q3	-6.9, 4.4	-9.8, 10.8	
Min, Max	-22.3, 55.4	-52.9, 71.1	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	46	27	
n [2]	26	23	
MMRM: Least Squares Mean [SE] (95% CI)	2.60 [3.76] (-4.90, 10.11)		1.42 [3.93] (-6.42, 9.26)
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.18 [5.40] (-9.59, 11.95)		
MMRM: P-value	0.83		
Corrected Hedges' g (95% CI)	0.061 (-0.500, 0.622)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.44		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
SF3602-Physical Component Summary at Baseline		
n	50	29
Mean (SD)	37.5 (8.84)	35.4 (8.61)
Median	37.1	33.5
Q1, Q3	30.1, 43.1	30.1, 39.6
Min, Max	23.2, 55.7	21.4, 53.6
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
SF3602-Physical Component Summary at Week 4		
n	57	31
Mean (SD)	38.0 (9.57)	35.9 (7.77)
Median	37.2	34.6
Q1, Q3	31.3, 43.3	31.2, 42.1
Min, Max	19.5, 57.7	17.9, 49.1
Return Rate (%)	86%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	86%	84%
Change in SF3602-Physical Component Summary at Week 4 from Baseline		
n	44	26
Mean (SD)	-0.2 (8.42)	-0.3 (5.15)
Median	0.9	-0.6
Q1, Q3	-3.1, 4.6	-3.9, 3.8
Min, Max	-26.5, 15.5	-9.9, 10.1

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	46	27	
n [2]	44	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.11 [1.10] (-2.09, 2.31)		-0.50 [1.32] (-3.13, 2.13)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.61 [1.71] (-2.81, 4.03)		
MMRM: P-value	0.72		
Corrected Hedges' g (95% CI)	0.085 (-0.400, 0.570)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.43		
Percent Change in SF3602-Physical Component Summary at Week 4 from Baseline			
n	44	26	
Mean (SD)	1.9 (21.96)	0.9 (16.96)	
Median	2.4	-1.6	
Q1, Q3	-9.6, 13.0	-8.9, 13.2	
Min, Max	-56.3, 65.1	-29.1, 47.1	
Difference in Percent Change from Baseline at Week 4			
n [1]	46	27	
n [2]	44	26	
MMRM: Least Squares Mean [SE] (95% CI)	3.21 [3.01] (-2.81, 9.22)		0.20 [3.58] (-6.94, 7.34)
MMRM: Least Squares Mean Difference [SE] (95% CI)	3.01 [4.66] (-6.29, 12.31)		
MMRM: P-value	0.52		
Corrected Hedges' g (95% CI)	0.154 (-0.332, 0.639)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.61		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
SF3602-Physical Component Summary at Week 8		
n	56	27
Mean (SD)	37.7 (8.85)	36.5 (8.52)
Median	36.2	35.4
Q1, Q3	30.9, 43.5	31.6, 44.0
Min, Max	23.1, 57.2	15.0, 50.6
Return Rate (%)	85%	69%
Number of Subjects in Risk	61	36
Return Rate in Risk (%)	92%	75%
Change in SF3602-Physical Component Summary at Week 8 from Baseline		
n	44	24
Mean (SD)	0.0 (7.39)	-0.1 (5.28)
Median	1.2	-1.2
Q1, Q3	-4.7, 4.3	-3.7, 4.8
Min, Max	-26.6, 16.7	-9.6, 10.0
Difference in Change from Baseline at Week 8		
n [1]	46	27
n [2]	44	24
MMRM: Least Squares Mean [SE] (95% CI)	0.01 [1.03] (-2.05, 2.08)	-0.33 [1.22] (-2.78, 2.11)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.35 [1.59] (-2.82, 3.52)	
MMRM: P-value	0.83	
Corrected Hedges' g (95% CI)	0.052 (-0.445, 0.550)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.42	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in SF3602-Physical Component Summary at Week 8 from Baseline		
n	44	24
Mean (SD)	2.4 (20.75)	0.5 (16.28)
Median	3.7	-3.8
Q1, Q3	-11.8, 12.3	-8.4, 12.6
Min, Max	-53.3, 70.1	-39.0, 36.4
Difference in Percent Change from Baseline at Week 8		
n [1]	46	27
n [2]	44	24
MMRM: Least Squares Mean [SE] (95% CI)	3.06 [2.93] (-2.78, 8.90)	-0.24 [3.47] (-7.18, 6.69)
MMRM: Least Squares Mean Difference [SE] (95% CI)	3.30 [4.51] (-5.70, 12.30)	
MMRM: P-value	0.47	
Corrected Hedges' g (95% CI)	0.175 (-0.323, 0.673)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.33	
SF3602-Physical Component Summary at Week 12		
n	49	30
Mean (SD)	38.7 (9.27)	34.9 (8.82)
Median	36.0	33.6
Q1, Q3	31.9, 46.7	28.3, 43.4
Min, Max	23.0, 58.1	16.2, 50.6
Return Rate (%)	74%	77%
Number of Subjects in Risk	59	33
Return Rate in Risk (%)	83%	91%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in SF3602-Physical Component Summary at Week 12 from Baseline		
n	36	26
Mean (SD)	0.4 (7.13)	-0.8 (6.31)
Median	0.3	-0.9
Q1, Q3	-4.1, 5.4	-4.8, 1.8
Min, Max	-15.2, 12.2	-13.8, 16.3
Difference in Change from Baseline at Week 12		
n [1]	46	27
n [2]	36	26
MMRM: Least Squares Mean [SE] (95% CI)	0.32 [1.17] (-2.02, 2.66)	-1.01 [1.37] (-3.74, 1.72)
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.33 [1.79] (-2.24, 4.90)	
MMRM: P-value	0.46	
Corrected Hedges' g (95% CI)	0.188 (-0.318, 0.693)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.13	
Percent Change in SF3602-Physical Component Summary at Week 12 from Baseline		
n	36	26
Mean (SD)	2.9 (19.11)	-1.3 (18.81)
Median	1.1	-2.4
Q1, Q3	-10.7, 17.3	-13.9, 4.8
Min, Max	-32.0, 52.5	-34.1, 59.4

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 12			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	4.18 [3.31] (-2.42, 10.79)		-1.84 [3.88] (-9.58, 5.89)
MMRM: Least Squares Mean Difference [SE] (95% CI)	6.03 [5.07] (-4.10, 16.15)		
MMRM: P-value	0.24		
Corrected Hedges' g (95% CI)	0.300 (-0.207, 0.808)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.10		
SF3602-Physical Component Summary at Week 16			
n	47	30	
Mean (SD)	38.4 (9.25)	35.3 (8.57)	
Median	35.1	36.8	
Q1, Q3	30.7, 48.3	30.5, 41.0	
Min, Max	23.2, 56.3	16.9, 52.9	
Return Rate (%)	71%	77%	
Number of Subjects in Risk	56	33	
Return Rate in Risk (%)	84%	91%	
Change in SF3602-Physical Component Summary at Week 16 from Baseline			
n	36	26	
Mean (SD)	1.7 (7.39)	-1.5 (5.66)	
Median	1.2	-2.0	
Q1, Q3	-3.1, 4.9	-4.8, 0.7	
Min, Max	-13.3, 24.6	-12.0, 14.0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.28 [1.16] (-2.04, 2.61)	-1.65 [1.34] (-4.32, 1.02)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	1.93 [1.76] (-1.59, 5.45)		
MMRM: P-value	0.28		
Corrected Hedges' g (95% CI)	0.275 (-0.231, 0.782)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.019		
Percent Change in SF3602-Physical Component Summary at Week 16 from Baseline			
n	36	26	
Mean (SD)	7.3 (24.37)	-3.4 (17.27)	
Median	3.8	-6.2	
Q1, Q3	-8.6, 13.0	-13.3, 1.4	
Min, Max	-25.3, 103.4	-33.3, 51.3	
Difference in Percent Change from Baseline at Week 16			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	3.81 [3.53] (-3.23, 10.85)	-3.89 [4.09] (-12.05, 4.27)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	7.70 [5.38] (-3.03, 18.43)		
MMRM: P-value	0.16		
Corrected Hedges' g (95% CI)	0.362 (-0.147, 0.870)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.017		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
SF3602-Physical Component Summary at Week 20		
n	38	29
Mean (SD)	39.3 (7.91)	36.7 (9.08)
Median	38.7	37.8
Q1, Q3	33.1, 43.4	30.9, 44.5
Min, Max	25.5, 59.6	18.1, 52.4
Return Rate (%)	58%	74%
Number of Subjects in Risk	51	32
Return Rate in Risk (%)	75%	91%
Change in SF3602-Physical Component Summary at Week 20 from Baseline		
n	30	24
Mean (SD)	2.2 (8.03)	1.2 (7.02)
Median	4.0	1.2
Q1, Q3	-3.1, 7.2	-1.6, 5.2
Min, Max	-19.7, 15.1	-18.0, 15.3
Difference in Change from Baseline at Week 20		
n [1]	46	27
n [2]	30	24
MMRM: Least Squares Mean [SE] (95% CI)	0.52 [1.28] (-2.02, 3.07)	0.78 [1.47] (-2.15, 3.71)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.26 [1.94] (-4.12, 3.61)	
MMRM: P-value	0.90	
Corrected Hedges' g (95% CI)	-0.036 (-0.572, 0.501)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.087	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in SF3602-Physical Component Summary at Week 20 from Baseline		
n	30	24
Mean (SD)	9.8 (23.16)	4.9 (20.83)
Median	10.1	3.2
Q1, Q3	-8.0, 26.5	-5.2, 16.2
Min, Max	-37.3, 63.5	-49.7, 50.9
Difference in Percent Change from Baseline at Week 20		
n [1]	46	27
n [2]	30	24
MMRM: Least Squares Mean [SE] (95% CI)	6.07 [3.44] (-0.80, 12.94)	3.83 [3.87] (-3.90, 11.55)
MMRM: Least Squares Mean Difference [SE] (95% CI)	2.24 [5.15] (-8.05, 12.53)	
MMRM: P-value	0.67	
Corrected Hedges' g (95% CI)	0.117 (-0.420, 0.654)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.100	
SF3602-Physical Component Summary at Week 24		
n	37	29
Mean (SD)	38.1 (9.08)	34.0 (9.53)
Median	36.4	32.3
Q1, Q3	31.0, 43.6	27.5, 39.2
Min, Max	22.6, 59.5	18.6, 51.4
Return Rate (%)	56%	74%
Number of Subjects in Risk	48	31
Return Rate in Risk (%)	77%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in SF3602-Physical Component Summary at Week 24 from Baseline			
n	26	23	
Mean (SD)	1.9 (7.90)	-1.6 (4.11)	
Median	1.9	-1.7	
Q1, Q3	-2.4, 5.6	-3.6, 1.0	
Min, Max	-17.3, 19.8	-10.4, 7.2	
Difference in Change from Baseline at Week 24			
n [1]	46	27	
n [2]	26	23	
MMRM: Least Squares Mean [SE] (95% CI)	0.45 [1.16] (-1.87, 2.77)		-2.44 [1.28] (-5.01, 0.12)
MMRM: Least Squares Mean Difference [SE] (95% CI)	2.89 [1.72] (-0.54, 6.33)		
MMRM: P-value	0.098		
Corrected Hedges' g (95% CI)	0.472 (-0.097, 1.040)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.019		
Percent Change in SF3602-Physical Component Summary at Week 24 from Baseline			
n	26	23	
Mean (SD)	8.4 (24.70)	-4.2 (10.23)	
Median	6.1	-4.2	
Q1, Q3	-5.7, 18.4	-10.4, 3.1	
Min, Max	-33.3, 83.3	-24.8, 16.4	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	46	27	
n [2]	26	23	
MMRM: Least Squares Mean [SE] (95% CI)	4.85 [3.29] (-1.72, 11.41)	-6.52 [3.58] (-13.65, 0.62)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	11.36 [4.83] (1.72, 21.01)		
MMRM: P-value	0.022		
Corrected Hedges' g (95% CI)	0.660 (0.084, 1.236)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.015		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
SF3602-Mental Component Summary at Baseline		
n	50	29
Mean (SD)	47.2 (10.56)	45.5 (12.53)
Median	47.3	50.8
Q1, Q3	40.7, 54.5	38.3, 55.7
Min, Max	19.4, 67.6	20.2, 60.3
Return Rate (%)	76%	74%
Number of Subjects in Risk	66	39
Return Rate in Risk (%)	76%	74%
SF3602-Mental Component Summary at Week 4		
n	57	31
Mean (SD)	47.8 (10.53)	46.5 (11.11)
Median	51.0	48.4
Q1, Q3	42.1, 55.2	37.6, 56.3
Min, Max	23.2, 63.1	14.0, 61.0
Return Rate (%)	86%	79%
Number of Subjects in Risk	66	37
Return Rate in Risk (%)	86%	84%
Change in SF3602-Mental Component Summary at Week 4 from Baseline		
n	44	26
Mean (SD)	0.3 (9.64)	1.2 (9.05)
Median	-0.3	0.7
Q1, Q3	-6.8, 7.9	-4.1, 8.8
Min, Max	-22.6, 20.8	-17.8, 17.4

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 4			
n [1]	46	27	
n [2]	44	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.44 [1.34] (-2.23, 3.11)		0.43 [1.61] (-2.78, 3.63)
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.01 [2.08] (-4.14, 4.15)		
MMRM: P-value	1.00		
Corrected Hedges' g (95% CI)	0.001 (-0.484, 0.486)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.67		
Percent Change in SF3602-Mental Component Summary at Week 4 from Baseline			
n	44	26	
Mean (SD)	3.3 (23.05)	6.4 (25.95)	
Median	-0.8	1.6	
Q1, Q3	-11.9, 20.5	-7.8, 22.4	
Min, Max	-44.7, 60.0	-38.1, 86.3	
Difference in Percent Change from Baseline at Week 4			
n [1]	46	27	
n [2]	44	26	
MMRM: Least Squares Mean [SE] (95% CI)	4.15 [3.34] (-2.52, 10.81)		4.52 [4.02] (-3.51, 12.55)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.37 [5.20] (-10.76, 10.01)		
MMRM: P-value	0.94		
Corrected Hedges' g (95% CI)	-0.017 (-0.502, 0.468)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.58		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
SF3602-Mental Component Summary at Week 8			
n	56	27	
Mean (SD)	47.2 (11.60)	48.7 (9.92)	
Median	50.5	49.7	
Q1, Q3	39.0, 57.1	43.7, 56.8	
Min, Max	13.7, 64.6	16.4, 59.9	
Return Rate (%)	85%	69%	
Number of Subjects in Risk	61	36	
Return Rate in Risk (%)	92%	75%	
Change in SF3602-Mental Component Summary at Week 8 from Baseline			
n	44	24	
Mean (SD)	-0.9 (8.76)	1.9 (8.72)	
Median	-0.8	1.3	
Q1, Q3	-5.9, 4.0	-3.9, 7.5	
Min, Max	-23.2, 18.3	-14.3, 23.6	
Difference in Change from Baseline at Week 8			
n [1]	46	27	
n [2]	44	24	
MMRM: Least Squares Mean [SE] (95% CI)	-0.94 [1.32] (-3.58, 1.70)	2.26 [1.60] (-0.94, 5.47)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-3.21 [2.06] (-7.33, 0.91)		
MMRM: P-value	0.13		
Corrected Hedges' g (95% CI)	-0.374 (-0.876, 0.127)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.31		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Percent Change in SF3602-Mental Component Summary at Week 8 from Baseline			
n	44	24	
Mean (SD)	-0.7 (21.27)	9.0 (29.56)	
Median	-1.7	2.3	
Q1, Q3	-11.3, 9.9	-7.0, 21.8	
Min, Max	-62.9, 46.2	-27.7, 116.7	
Difference in Percent Change from Baseline at Week 8			
n [1]	46	27	
n [2]	44	24	
MMRM: Least Squares Mean [SE] (95% CI)	-0.14 [3.53] (-7.19, 6.91)		9.85 [4.34] (1.18, 18.52)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-9.99 [5.57] (-21.11, 1.13)		
MMRM: P-value	0.078		
Corrected Hedges' g (95% CI)	-0.435 (-0.938, 0.068)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.38		
SF3602-Mental Component Summary at Week 12			
n	49	30	
Mean (SD)	47.7 (11.94)	47.5 (11.18)	
Median	47.9	50.3	
Q1, Q3	37.9, 58.6	36.6, 57.5	
Min, Max	24.8, 67.0	14.0, 60.1	
Return Rate (%)	74%	77%	
Number of Subjects in Risk	59	33	
Return Rate in Risk (%)	83%	91%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Change in SF3602-Mental Component Summary at Week 12 from Baseline		
n	36	26
Mean (SD)	-1.3 (9.87)	0.0 (7.96)
Median	-0.4	0.6
Q1, Q3	-8.3, 3.9	-7.8, 5.7
Min, Max	-19.6, 23.9	-14.2, 16.0
Difference in Change from Baseline at Week 12		
n [1]	46	27
n [2]	36	26
MMRM: Least Squares Mean [SE] (95% CI)	-1.25 [1.39] (-4.03, 1.53)	-0.08 [1.60] (-3.27, 3.11)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.17 [2.11] (-5.37, 3.03)	
MMRM: P-value	0.58	
Corrected Hedges' g (95% CI)	-0.139 (-0.645, 0.366)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.71	
Percent Change in SF3602-Mental Component Summary at Week 12 from Baseline		
n	36	26
Mean (SD)	0.1 (25.41)	3.4 (24.39)
Median	-0.7	1.1
Q1, Q3	-17.3, 7.1	-13.5, 10.6
Min, Max	-38.6, 79.3	-38.1, 79.2

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 12			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.41 [3.62] (-6.81, 7.63)		3.37 [4.22] (-5.06, 11.79)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.96 [5.53] (-13.99, 8.07)		
MMRM: P-value	0.59		
Corrected Hedges' g (95% CI)	-0.135 (-0.640, 0.370)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.75		
SF3602-Mental Component Summary at Week 16			
n	47	30	
Mean (SD)	48.2 (11.60)	47.2 (11.84)	
Median	50.6	51.7	
Q1, Q3	41.6, 58.0	39.7, 55.6	
Min, Max	22.8, 62.4	15.4, 60.0	
Return Rate (%)	71%	77%	
Number of Subjects in Risk	56	33	
Return Rate in Risk (%)	84%	91%	
Change in SF3602-Mental Component Summary at Week 16 from Baseline			
n	36	26	
Mean (SD)	-0.6 (9.22)	-0.3 (7.99)	
Median	-1.0	1.7	
Q1, Q3	-6.2, 5.9	-4.6, 4.7	
Min, Max	-22.9, 20.4	-23.3, 11.3	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Change from Baseline at Week 16			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	-0.52 [1.44] (-3.40, 2.36)		-0.41 [1.63] (-3.67, 2.85)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.11 [2.16] (-4.43, 4.21)		
MMRM: P-value	0.96		
Corrected Hedges' g (95% CI)	-0.012 (-0.517, 0.492)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.71		
Percent Change in SF3602-Mental Component Summary at Week 16 from Baseline			
n	36	26	
Mean (SD)	0.4 (21.31)	1.1 (19.15)	
Median	-1.9	3.0	
Q1, Q3	-12.0, 14.0	-7.9, 15.7	
Min, Max	-50.1, 51.4	-41.9, 30.2	
Difference in Percent Change from Baseline at Week 16			
n [1]	46	27	
n [2]	36	26	
MMRM: Least Squares Mean [SE] (95% CI)	0.98 [3.41] (-5.82, 7.79)		1.08 [3.80] (-6.50, 8.66)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.09 [5.07] (-10.21, 10.02)		
MMRM: P-value	0.99		
Corrected Hedges' g (95% CI)	-0.005 (-0.509, 0.500)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.57		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
SF3602-Mental Component Summary at Week 20			
n	38	29	
Mean (SD)	50.0 (10.86)	48.0 (11.28)	
Median	51.2	50.3	
Q1, Q3	42.6, 57.2	41.4, 56.6	
Min, Max	26.8, 71.2	21.3, 63.3	
Return Rate (%)	58%	74%	
Number of Subjects in Risk	51	32	
Return Rate in Risk (%)	75%	91%	
Change in SF3602-Mental Component Summary at Week 20 from Baseline			
n	30	24	
Mean (SD)	0.4 (7.77)	0.7 (7.67)	
Median	-0.9	-0.7	
Q1, Q3	-5.3, 6.0	-2.9, 6.0	
Min, Max	-14.4, 21.5	-19.5, 16.1	
Difference in Change from Baseline at Week 20			
n [1]	46	27	
n [2]	30	24	
MMRM: Least Squares Mean [SE] (95% CI)	0.52 [1.36] (-2.18, 3.23)	0.30 [1.47] (-2.64, 3.25)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	0.22 [1.99] (-3.75, 4.19)		
MMRM: P-value	0.91		
Corrected Hedges' g (95% CI)	0.030 (-0.507, 0.566)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.73		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)
Percent Change in SF3602-Mental Component Summary at Week 20 from Baseline		
n	30	24
Mean (SD)	1.5 (17.45)	4.6 (22.18)
Median	-1.6	-1.7
Q1, Q3	-10.5, 12.4	-6.6, 12.5
Min, Max	-28.8, 54.1	-38.3, 79.8
Difference in Percent Change from Baseline at Week 20		
n [1]	46	27
n [2]	30	24
MMRM: Least Squares Mean [SE] (95% CI)	2.75 [3.31] (-3.86, 9.36)	3.81 [3.64] (-3.45, 11.08)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-1.06 [4.89] (-10.81, 8.69)	
MMRM: P-value	0.83	
Corrected Hedges' g (95% CI)	-0.058 (-0.595, 0.479)	
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.78	
SF3602-Mental Component Summary at Week 24		
n	37	29
Mean (SD)	49.8 (10.80)	47.4 (12.20)
Median	49.5	52.8
Q1, Q3	45.3, 59.6	36.0, 56.3
Min, Max	27.5, 67.4	13.5, 62.9
Return Rate (%)	56%	74%
Number of Subjects in Risk	48	31
Return Rate in Risk (%)	77%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Change in SF3602-Mental Component Summary at Week 24 from Baseline			
n	26	23	
Mean (SD)	-0.7 (7.64)	0.7 (10.38)	
Median	-1.9	2.3	
Q1, Q3	-5.9, 3.2	-3.7, 7.4	
Min, Max	-13.5, 19.9	-28.2, 14.7	
Difference in Change from Baseline at Week 24			
n [1]	46	27	
n [2]	26	23	
MMRM: Least Squares Mean [SE] (95% CI)	-0.42 [1.60] (-3.60, 2.77)	0.50 [1.69] (-2.87, 3.88)	
MMRM: Least Squares Mean Difference [SE] (95% CI)	-0.92 [2.32] (-5.54, 3.70)		
MMRM: P-value	0.69		
Corrected Hedges' g (95% CI)	-0.111 (-0.673, 0.450)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.94		
Percent Change in SF3602-Mental Component Summary at Week 24 from Baseline			
n	26	23	
Mean (SD)	-0.1 (17.30)	5.3 (27.16)	
Median	-3.4	4.0	
Q1, Q3	-11.2, 5.7	-6.2, 19.5	
Min, Max	-26.9, 50.3	-48.6, 72.7	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

Data Extracted: CRF data: 25JUN2019

Table 2.8001: Analysis of SF-36v2, Change and % Change from Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	MMB (N=66)	BAT (N=39)	
Difference in Percent Change from Baseline at Week 24			
n [1]	46	27	
n [2]	26	23	
MMRM: Least Squares Mean [SE] (95% CI)	1.62 [3.74] (-5.85, 9.08)		4.56 [3.97] (-3.36, 12.49)
MMRM: Least Squares Mean Difference [SE] (95% CI)	-2.94 [5.42] (-13.77, 7.88)		
MMRM: P-value	0.59		
Corrected Hedges' g (95% CI)	-0.152 (-0.714, 0.410)		
Stratified Wilcoxon Rank Sum (van Elteren) p-value	0.80		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
SF-36v2 = Short Form Questionnaire-36 version 2.
MMRM model included Treatment, Baseline value, Baseline TD (yes, no) and Baseline TSS (<18, >=18),
Visit and Treatment by Visit interaction as covariates.
[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.

2.10 Sicherheit

2.10.1 Zusammenfassung

GSK Oncology
Study GS-US-352-1214

Table 3.0301: TEAEs: Overall Summary
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	ET Phase (Week 24 Onward)			Overall Exposed to MMB
	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)	Total (N=96)
Subjects With Any				
TEAE	42 (97.7%)	30 (100.0%)	72 (98.6%)	96 (100.0%)
TEAE with Grade >=3	31 (72.1%)	22 (73.3%)	53 (72.6%)	77 (80.2%)
TEAE with Grade 3 or 4	28 (65.1%)	22 (73.3%)	50 (68.5%)	74 (77.1%)
TEAE Related to Study Drug	24 (55.8%)	23 (76.7%)	47 (64.4%)	78 (81.3%)
TEAE Related to Study Drug with Grade >=3	12 (27.9%)	13 (43.3%)	25 (34.2%)	41 (42.7%)
Serious TEAE	26 (60.5%)	13 (43.3%)	39 (53.4%)	53 (55.2%)
Serious TEAE Related to Study Drug	4 (9.3%)	4 (13.3%)	8 (11.0%)	15 (15.6%)
Non-Fatal SAEs	25 (58.1%)	13 (43.3%)	38 (52.1%)	52 (54.2%)
TEAE Leading to Premature Discontinuation of Study Drug	13 (30.2%)	15 (50.0%)	28 (38.4%)	42 (43.8%)
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug	15 (34.9%)	12 (40.0%)	27 (37.0%)	32 (33.3%)
TEAE Leading to Death	12 (27.9%)	2 (6.7%)	14 (19.2%)	18 (18.8%)
TEAE of Interest				
Peripheral Neuropathy SMQ (Narrow Term Only)	5 (11.6%)	7 (23.3%)	12 (16.4%)	18 (18.8%)
Peripheral Neuropathy SMQ (Narrow Term Only) -> Study Drug Disc	1 (2.3%)	2 (6.7%)	3 (4.1%)	4 (4.2%)
Non-Hematological	42 (97.7%)	30 (100.0%)	72 (98.6%)	96 (100.0%)
Cataract	1 (2.3%)	0	1 (1.4%)	4 (4.2%)
First Dose Effect	-	2 (6.7%)	-	3 (3.1%)
Serious TEAEs for First Dose Effect	-	0	-	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Severity grades were defined by CTCAE Version 4.03
TEAE = Treatment-Emergent Adverse Event

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-et.sas V.03.05 Output file: t-aebrief-et.pdf 24AUG2023:16:50

Table 3.1101: TEAEs of Grade 2 or less
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
Number of subjects, n(%)	64 (97.0%)	34 (87.2%)	98 (93.3%)	42 (97.7%)	29 (96.7%)	71 (97.3%)
Unadjusted Relative Risk (95% CI)	1.11 (0.98, 1.26)					
p-value [1]	0.10					
Unadjusted Odds Ratio (95% CI)	4.71 (0.87, 25.55)					
p-value [1]	0.073					
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.01, 0.21)					
Adjusted Relative Risk (95% CI) [2]	1.11 (0.97, 1.26)					
p-value [2]	0.13					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Severity grades were defined by CTCAE Version 4.03.
TEAE = Treatment-Emergent Adverse Event.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-gle2-gba.sas V.03.05 Output file: t-aesum-gle2-gba.pdf 24AUG2023:16:49

Table 3.0201: TEAEs: Overall Summary
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
TEAE						
Number of subjects, n(%)	66 (100.0%)	35 (89.7%)	101 (96.2%)	42 (97.7%)	30 (100.0%)	72 (98.6%)
Unadjusted Relative Risk (95% CI)	1.12 (1.00, 1.25)					
p-value [1]	0.051					
Unadjusted Odds Ratio (95% CI)	16.86 (0.88, 322.13)					
p-value [1]	0.061					
Unadjusted Absolute Risk Difference (95% CI)	0.11 (0.00, 0.21)					
Adjusted Relative Risk (95% CI) [2]	1.11 (1.00, 1.23)					
p-value [2]	0.048					
TEAE with Grade >=3						
Number of subjects, n(%)	40 (60.6%)	18 (46.2%)	58 (55.2%)	31 (72.1%)	22 (73.3%)	53 (72.6%)
Unadjusted Relative Risk (95% CI)	1.31 (0.89, 1.94)					
p-value [1]	0.17					
Unadjusted Odds Ratio (95% CI)	1.79 (0.81, 3.99)					
p-value [1]	0.15					
Unadjusted Absolute Risk Difference (95% CI)	0.14 (-0.05, 0.34)					
Adjusted Relative Risk (95% CI) [2]	1.35 (0.91, 1.98)					
p-value [2]	0.13					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Severity grades were defined by CTCAE Version 4.03
TEAE = Treatment-Emergent Adverse Event
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.0201: TEAEs: Overall Summary
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
TEAE with Grade 3 or 4						
Number of subjects, n(%)	39 (59.1%)	18 (46.2%)	57 (54.3%)	28 (65.1%)	22 (73.3%)	50 (68.5%)
Unadjusted Relative Risk (95% CI)	1.28 (0.86, 1.90)					
p-value [1]	0.22					
Unadjusted Odds Ratio (95% CI)	1.69 (0.76, 3.74)					
p-value [1]	0.20					
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.07, 0.33)					
Adjusted Relative Risk (95% CI) [2]	1.31 (0.88, 1.94)					
p-value [2]	0.18					
TEAE Related to Study Drug						
Number of subjects, n(%)	49 (74.2%)	15 (38.5%)	64 (61.0%)	24 (55.8%)	23 (76.7%)	47 (64.4%)
Unadjusted Relative Risk (95% CI)	1.93 (1.27, 2.94)					
p-value [1]	0.002					
Unadjusted Odds Ratio (95% CI)	4.61 (1.97, 10.78)					
p-value [1]	<0.001					
Unadjusted Absolute Risk Difference (95% CI)	0.36 (0.17, 0.54)					
Adjusted Relative Risk (95% CI) [2]	1.96 (1.30, 2.97)					
p-value [2]	0.001					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Severity grades were defined by CTCAE Version 4.03
TEAE = Treatment-Emergent Adverse Event
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-rt-gba.sas V.03.05 Output file: t-aesum-rt-gba.pdf 24AUG2023:16:49

Table 3.0201: TEAEs: Overall Summary
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
TEAE Related to Study Drug with Grade >=3						
Number of subjects, n(%)	20 (30.3%)	8 (20.5%)	28 (26.7%)	12 (27.9%)	13 (43.3%)	25 (34.2%)
Unadjusted Relative Risk (95% CI)	1.48 (0.72, 3.03)					
p-value [1]	0.29					
Unadjusted Odds Ratio (95% CI)	1.68 (0.66, 4.30)					
p-value [1]	0.28					
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.07, 0.27)					
Adjusted Relative Risk (95% CI) [2]	1.45 (0.70, 3.00)					
p-value [2]	0.32					
Serious TEAE						
Number of subjects, n(%)	23 (34.8%)	9 (23.1%)	32 (30.5%)	26 (60.5%)	13 (43.3%)	39 (53.4%)
Unadjusted Relative Risk (95% CI)	1.51 (0.78, 2.93)					
p-value [1]	0.22					
Unadjusted Odds Ratio (95% CI)	1.78 (0.72, 4.39)					
p-value [1]	0.21					
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.06, 0.29)					
Adjusted Relative Risk (95% CI) [2]	1.44 (0.74, 2.80)					
p-value [2]	0.28					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Severity grades were defined by CTCAE Version 4.03
TEAE = Treatment-Emergent Adverse Event
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.0201: TEAEs: Overall Summary
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
Serious TEAE Related to Study Drug						
Number of subjects, n(%)	7 (10.6%)	2 (5.1%)	9 (8.6%)	4 (9.3%)	4 (13.3%)	8 (11.0%)
Unadjusted Relative Risk (95% CI)	2.07 (0.45, 9.46)					
p-value [1]	0.35					
Unadjusted Odds Ratio (95% CI)	2.19 (0.43, 11.14)					
p-value [1]	0.34					
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.05, 0.16)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Non-Fatal SAEs						
Number of subjects, n(%)	23 (34.8%)	8 (20.5%)	31 (29.5%)	25 (58.1%)	13 (43.3%)	38 (52.1%)
Unadjusted Relative Risk (95% CI)	1.70 (0.84, 3.42)					
p-value [1]	0.14					
Unadjusted Odds Ratio (95% CI)	2.07 (0.82, 5.24)					
p-value [1]	0.12					
Unadjusted Absolute Risk Difference (95% CI)	0.14 (-0.03, 0.31)					
Adjusted Relative Risk (95% CI) [2]	1.65 (0.82, 3.31)					
p-value [2]	0.16					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Severity grades were defined by CTCAE Version 4.03
TEAE = Treatment-Emergent Adverse Event
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-rt-gba.sas V.03.05 Output file: t-aesum-rt-gba.pdf 24AUG2023:16:49

Table 3.0201: TEAEs: Overall Summary
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
TEAE Leading to Premature Discontinuation of Study Drug						
Number of subjects, n(%)	14 (21.2%)	1 (2.6%)	15 (14.3%)	13 (30.2%)	15 (50.0%)	28 (38.4%)
Unadjusted Relative Risk (95% CI)	8.27 (1.13, 60.51)					
p-value [1]	0.037					
Unadjusted Odds Ratio (95% CI)	10.23 (1.29, 81.20)					
p-value [1]	0.028					
Unadjusted Absolute Risk Difference (95% CI)	0.19 (0.08, 0.30)					
Adjusted Relative Risk (95% CI) [2]	8.66 (1.16, 64.73)					
p-value [2]	0.035					
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug						
Number of subjects, n(%)	9 (13.6%)	8 (20.5%)	17 (16.2%)	15 (34.9%)	12 (40.0%)	27 (37.0%)
Unadjusted Relative Risk (95% CI)	0.66 (0.28, 1.58)					
p-value [1]	0.36					
Unadjusted Odds Ratio (95% CI)	0.61 (0.21, 1.74)					
p-value [1]	0.36					
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.22, 0.08)					
Adjusted Relative Risk (95% CI) [2]	0.73 (0.30, 1.78)					
p-value [2]	0.49					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Severity grades were defined by CTCAE Version 4.03
TEAE = Treatment-Emergent Adverse Event
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.0201: TEAEs: Overall Summary
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
TEAE Leading to Death						
Number of subjects, n(%)	4 (6.1%)	4 (10.3%)	8 (7.6%)	12 (27.9%)	2 (6.7%)	14 (19.2%)
Unadjusted Relative Risk (95% CI)	0.59 (0.16, 2.23)					
p-value [1]	0.44					
Unadjusted Odds Ratio (95% CI)	0.56 (0.13, 2.40)					
p-value [1]	0.44					
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.15, 0.07)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Severity grades were defined by CTCAE Version 4.03
TEAE = Treatment-Emergent Adverse Event
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-rt-gba.sas V.03.05 Output file: t-aesum-rt-gba.pdf 24AUG2023:16:49

2.10.2 UE

GSK Oncology
Study GS-US-352-1214

Table 3.0901: TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Any TEAE						
Number of Subjects With Any Event	66 (100.0%)	35 (89.7%)	101 (96.2%)	42 (97.7%)	30 (100.0%)	72 (98.6%)
Unadjusted Relative Risk (95% CI)	1.12 (1.00, 1.25)					
p-value [1]	0.051					
Unadjusted Odds Ratio (95% CI)	16.86 (0.88, 322.13)					
p-value [1]	0.061					
Unadjusted Absolute Risk Difference (95% CI)	0.11 (0.00, 0.21)					
Adjusted Relative Risk (95% CI) [2]	1.11 (1.00, 1.23)					
p-value [2]	0.048					
Gastrointestinal disorders						
Any Event	40 (60.6%)	17 (43.6%)	57 (54.3%)	19 (44.2%)	21 (70.0%)	40 (54.8%)
Unadjusted Relative Risk (95% CI)	1.39 (0.93, 2.09)					
p-value [1]	0.11					
Unadjusted Odds Ratio (95% CI)	1.99 (0.89, 4.44)					
p-value [1]	0.093					
Unadjusted Absolute Risk Difference (95% CI)	0.17 (-0.03, 0.37)					
Adjusted Relative Risk (95% CI) [2]	1.45 (0.97, 2.16)					
p-value [2]	0.071					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.0901: TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Gastrointestinal disorders						
Diarrhoea	21 (31.8%)	5 (12.8%)	26 (24.8%)	13 (30.2%)	7 (23.3%)	20 (27.4%)
Unadjusted Relative Risk (95% CI)	2.48 (1.02, 6.05)					
p-value [1]	0.046					
Unadjusted Odds Ratio (95% CI)	3.17 (1.09, 9.27)					
p-value [1]	0.035					
Unadjusted Absolute Risk Difference (95% CI)	0.19 (0.04, 0.34)					
Adjusted Relative Risk (95% CI) [2]	2.18 (0.88, 5.35)					
p-value [2]	0.090					
Gastrointestinal disorders						
Nausea	12 (18.2%)	3 (7.7%)	15 (14.3%)	5 (11.6%)	5 (16.7%)	10 (13.7%)
Unadjusted Relative Risk (95% CI)	2.36 (0.71, 7.86)					
p-value [1]	0.16					
Unadjusted Odds Ratio (95% CI)	2.67 (0.70, 10.12)					
p-value [1]	0.15					
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.02, 0.23)					
Adjusted Relative Risk (95% CI) [2]	2.93 (0.99, 8.67)					
p-value [2]	0.053					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.0901: TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Gastrointestinal disorders						
Abdominal pain	10 (15.2%)	5 (12.8%)	15 (14.3%)	3 (7.0%)	3 (10.0%)	6 (8.2%)
Unadjusted Relative Risk (95% CI)	1.18 (0.44, 3.21)					
p-value [1]	0.74					
Unadjusted Odds Ratio (95% CI)	1.21 (0.38, 3.85)					
p-value [1]	0.74					
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.11, 0.16)					
Adjusted Relative Risk (95% CI) [2]	1.37 (0.53, 3.55)					
p-value [2]	0.52					
Gastrointestinal disorders						
Dyspepsia	7 (10.6%)	0	7 (6.7%)	1 (2.3%)	1 (3.3%)	2 (2.7%)
Unadjusted Relative Risk (95% CI)	8.96 (0.53, 152.64)					
p-value [1]	0.13					
Unadjusted Odds Ratio (95% CI)	9.96 (0.55, 179.34)					
p-value [1]	0.12					
Unadjusted Absolute Risk Difference (95% CI)	0.10 (0.02, 0.18)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.0901: TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Gastrointestinal disorders						
Abdominal pain upper	5 (7.6%)	1 (2.6%)	6 (5.7%)	1 (2.3%)	3 (10.0%)	4 (5.5%)
Unadjusted Relative Risk (95% CI)	2.95 (0.36, 24.38)					
p-value [1]	0.31					
Unadjusted Odds Ratio (95% CI)	3.11 (0.35, 27.69)					
p-value [1]	0.31					
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.03, 0.13)					
Adjusted Relative Risk (95% CI) [2]	3.11 (0.46, 20.97)					
p-value [2]	0.24					
Gastrointestinal disorders						
Vomiting	3 (4.5%)	1 (2.6%)	4 (3.8%)	2 (4.7%)	3 (10.0%)	5 (6.8%)
Unadjusted Relative Risk (95% CI)	1.77 (0.19, 16.46)					
p-value [1]	0.61					
Unadjusted Odds Ratio (95% CI)	1.81 (0.18, 18.03)					
p-value [1]	0.61					
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.05, 0.09)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.0901: TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC PT	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
Infections and infestations						
Any Event	34 (51.5%)	16 (41.0%)	50 (47.6%)	27 (62.8%)	18 (60.0%)	45 (61.6%)
Unadjusted Relative Risk (95% CI)	1.26 (0.81, 1.96)					
p-value [1]	0.31					
Unadjusted Odds Ratio (95% CI)	1.53 (0.69, 3.40)					
p-value [1]	0.30					
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.09, 0.30)					
Adjusted Relative Risk (95% CI) [2]	1.24 (0.79, 1.95)					
p-value [2]	0.34					
Infections and infestations						
Upper respiratory tract infection	7 (10.6%)	3 (7.7%)	10 (9.5%)	8 (18.6%)	5 (16.7%)	13 (17.8%)
Unadjusted Relative Risk (95% CI)	1.38 (0.38, 5.03)					
p-value [1]	0.63					
Unadjusted Odds Ratio (95% CI)	1.42 (0.35, 5.86)					
p-value [1]	0.62					
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.08, 0.14)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.0901: TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Infections and infestations						
Urinary tract infection	6 (9.1%)	3 (7.7%)	9 (8.6%)	6 (14.0%)	6 (20.0%)	12 (16.4%)
Unadjusted Relative Risk (95% CI)	1.18 (0.31, 4.46)					
p-value [1]	0.81					
Unadjusted Odds Ratio (95% CI)	1.20 (0.28, 5.10)					
p-value [1]	0.80					
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.09, 0.12)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Infections and infestations						
Pneumonia	3 (4.5%)	1 (2.6%)	4 (3.8%)	7 (16.3%)	3 (10.0%)	10 (13.7%)
Unadjusted Relative Risk (95% CI)	1.77 (0.19, 16.46)					
p-value [1]	0.61					
Unadjusted Odds Ratio (95% CI)	1.81 (0.18, 18.03)					
p-value [1]	0.61					
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.05, 0.09)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.0901: TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC PT	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
Infections and infestations						
Bronchitis	2 (3.0%)	0	2 (1.9%)	6 (14.0%)	3 (10.0%)	9 (12.3%)
Unadjusted Relative Risk (95% CI)	2.99 (0.15, 60.62)					
p-value [1]	0.48					
Unadjusted Odds Ratio (95% CI)	3.06 (0.14, 65.44)					
p-value [1]	0.47					
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.03, 0.08)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
General disorders and administration site conditions						
Any Event	33 (50.0%)	20 (51.3%)	53 (50.5%)	25 (58.1%)	19 (63.3%)	44 (60.3%)
Unadjusted Relative Risk (95% CI)	0.98 (0.66, 1.44)					
p-value [1]	0.90					
Unadjusted Odds Ratio (95% CI)	0.95 (0.43, 2.10)					
p-value [1]	0.90					
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.21, 0.19)					
Adjusted Relative Risk (95% CI) [2]	0.99 (0.67, 1.46)					
p-value [2]	0.94					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.0901: TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC PT	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
General disorders and administration site conditions						
Asthenia	13 (19.7%)	8 (20.5%)	21 (20.0%)	6 (14.0%)	9 (30.0%)	15 (20.5%)
Unadjusted Relative Risk (95% CI)	0.96 (0.44, 2.11)					
p-value [1]	0.92					
Unadjusted Odds Ratio (95% CI)	0.95 (0.35, 2.55)					
p-value [1]	0.92					
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.17, 0.15)					
Adjusted Relative Risk (95% CI) [2]	1.01 (0.48, 2.15)					
p-value [2]	0.97					
General disorders and administration site conditions						
Pyrexia	11 (16.7%)	3 (7.7%)	14 (13.3%)	11 (25.6%)	9 (30.0%)	20 (27.4%)
Unadjusted Relative Risk (95% CI)	2.17 (0.64, 7.29)					
p-value [1]	0.21					
Unadjusted Odds Ratio (95% CI)	2.40 (0.63, 9.20)					
p-value [1]	0.20					
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.03, 0.21)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.0901: TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC PT	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
General disorders and administration site conditions						
Fatigue	10 (15.2%)	7 (17.9%)	17 (16.2%)	4 (9.3%)	5 (16.7%)	9 (12.3%)
Unadjusted Relative Risk (95% CI)	0.84 (0.35, 2.04)					
p-value [1]	0.71					
Unadjusted Odds Ratio (95% CI)	0.82 (0.28, 2.35)					
p-value [1]	0.71					
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.18, 0.12)					
Adjusted Relative Risk (95% CI) [2]	0.93 (0.38, 2.30)					
p-value [2]	0.88					
General disorders and administration site conditions						
Oedema peripheral	8 (12.1%)	5 (12.8%)	13 (12.4%)	8 (18.6%)	3 (10.0%)	11 (15.1%)
Unadjusted Relative Risk (95% CI)	0.95 (0.33, 2.69)					
p-value [1]	0.92					
Unadjusted Odds Ratio (95% CI)	0.94 (0.28, 3.10)					
p-value [1]	0.92					
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.14, 0.12)					
Adjusted Relative Risk (95% CI) [2]	1.02 (0.36, 2.92)					
p-value [2]	0.97					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.0901: TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
General disorders and administration site conditions						
Early satiety	2 (3.0%)	4 (10.3%)	6 (5.7%)	1 (2.3%)	1 (3.3%)	2 (2.7%)
Unadjusted Relative Risk (95% CI)	0.30 (0.06, 1.54)					
p-value [1]	0.15					
Unadjusted Odds Ratio (95% CI)	0.27 (0.05, 1.57)					
p-value [1]	0.15					
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.18, 0.03)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Nervous system disorders						
Any Event	32 (48.5%)	8 (20.5%)	40 (38.1%)	18 (41.9%)	17 (56.7%)	35 (47.9%)
Unadjusted Relative Risk (95% CI)	2.36 (1.21, 4.60)					
p-value [1]	0.011					
Unadjusted Odds Ratio (95% CI)	3.65 (1.46, 9.11)					
p-value [1]	0.006					
Unadjusted Absolute Risk Difference (95% CI)	0.28 (0.10, 0.45)					
Adjusted Relative Risk (95% CI) [2]	2.39 (1.23, 4.67)					
p-value [2]	0.011					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.0901: TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Nervous system disorders						
Dizziness	11 (16.7%)	3 (7.7%)	14 (13.3%)	6 (14.0%)	3 (10.0%)	9 (12.3%)
Unadjusted Relative Risk (95% CI)	2.17 (0.64, 7.29)					
p-value [1]	0.21					
Unadjusted Odds Ratio (95% CI)	2.40 (0.63, 9.20)					
p-value [1]	0.20					
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.03, 0.21)					
Adjusted Relative Risk (95% CI) [2]	1.98 (0.59, 6.68)					
p-value [2]	0.27					
Nervous system disorders						
Headache	8 (12.1%)	3 (7.7%)	11 (10.5%)	0	6 (20.0%)	6 (8.2%)
Unadjusted Relative Risk (95% CI)	1.58 (0.44, 5.59)					
p-value [1]	0.48					
Unadjusted Odds Ratio (95% CI)	1.66 (0.41, 6.65)					
p-value [1]	0.48					
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.07, 0.16)					
Adjusted Relative Risk (95% CI) [2]	1.58 (0.45, 5.57)					
p-value [2]	0.47					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.0901: TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Nervous system disorders						
Peripheral sensory neuropathy	6 (9.1%)	0	6 (5.7%)	4 (9.3%)	6 (20.0%)	10 (13.7%)
Unadjusted Relative Risk (95% CI)	7.76 (0.45, 134.13)					
p-value [1]	0.16					
Unadjusted Odds Ratio (95% CI)	8.49 (0.47, 154.92)					
p-value [1]	0.15					
Unadjusted Absolute Risk Difference (95% CI)	0.08 (0.01, 0.16)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Nervous system disorders						
Paraesthesia	4 (6.1%)	1 (2.6%)	5 (4.8%)	1 (2.3%)	3 (10.0%)	4 (5.5%)
Unadjusted Relative Risk (95% CI)	2.36 (0.27, 20.40)					
p-value [1]	0.43					
Unadjusted Odds Ratio (95% CI)	2.45 (0.26, 22.76)					
p-value [1]	0.43					
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.04, 0.11)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.0901: TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC PT	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
Blood and lymphatic system disorders						
Any Event	26 (39.4%)	16 (41.0%)	42 (40.0%)	17 (39.5%)	20 (66.7%)	37 (50.7%)
Unadjusted Relative Risk (95% CI)	0.96 (0.59, 1.55)					
p-value [1]	0.87					
Unadjusted Odds Ratio (95% CI)	0.93 (0.42, 2.09)					
p-value [1]	0.87					
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.21, 0.18)					
Adjusted Relative Risk (95% CI) [2]	0.97 (0.60, 1.58)					
p-value [2]	0.91					
Blood and lymphatic system disorders						
Anaemia	13 (19.7%)	10 (25.6%)	23 (21.9%)	10 (23.3%)	9 (30.0%)	19 (26.0%)
Unadjusted Relative Risk (95% CI)	0.77 (0.37, 1.58)					
p-value [1]	0.47					
Unadjusted Odds Ratio (95% CI)	0.71 (0.28, 1.82)					
p-value [1]	0.48					
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.23, 0.11)					
Adjusted Relative Risk (95% CI) [2]	0.76 (0.38, 1.52)					
p-value [2]	0.44					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.0901: TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC PT	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
Blood and lymphatic system disorders						
Thrombocytopenia	11 (16.7%)	4 (10.3%)	15 (14.3%)	6 (14.0%)	8 (26.7%)	14 (19.2%)
Unadjusted Relative Risk (95% CI)	1.63 (0.56, 4.76)					
p-value [1]	0.38					
Unadjusted Odds Ratio (95% CI)	1.75 (0.52, 5.93)					
p-value [1]	0.37					
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.07, 0.20)					
Adjusted Relative Risk (95% CI) [2]	1.67 (0.53, 5.26)					
p-value [2]	0.38					
Blood and lymphatic system disorders						
Neutropenia	7 (10.6%)	1 (2.6%)	8 (7.6%)	2 (4.7%)	2 (6.7%)	4 (5.5%)
Unadjusted Relative Risk (95% CI)	4.14 (0.53, 32.38)					
p-value [1]	0.18					
Unadjusted Odds Ratio (95% CI)	4.51 (0.53, 38.11)					
p-value [1]	0.17					
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.01, 0.17)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.0901: TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Blood and lymphatic system disorders						
Splenic infarction	1 (1.5%)	0	1 (1.0%)	0	3 (10.0%)	3 (4.1%)
Unadjusted Relative Risk (95% CI)	1.79 (0.07, 42.92)					
p-value [1]	0.72					
Unadjusted Odds Ratio (95% CI)	1.81 (0.07, 45.50)					
p-value [1]	0.72					
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.04, 0.06)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Metabolism and nutrition disorders						
Any Event	25 (37.9%)	8 (20.5%)	33 (31.4%)	20 (46.5%)	9 (30.0%)	29 (39.7%)
Unadjusted Relative Risk (95% CI)	1.85 (0.93, 3.68)					
p-value [1]	0.082					
Unadjusted Odds Ratio (95% CI)	2.36 (0.94, 5.95)					
p-value [1]	0.068					
Unadjusted Absolute Risk Difference (95% CI)	0.17 (0.00, 0.35)					
Adjusted Relative Risk (95% CI) [2]	1.93 (0.95, 3.94)					
p-value [2]	0.070					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.0901: TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Metabolism and nutrition disorders						
Vitamin B1 deficiency	7 (10.6%)	1 (2.6%)	8 (7.6%)	5 (11.6%)	1 (3.3%)	6 (8.2%)
Unadjusted Relative Risk (95% CI)	4.14 (0.53, 32.38)					
p-value [1]	0.18					
Unadjusted Odds Ratio (95% CI)	4.51 (0.53, 38.11)					
p-value [1]	0.17					
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.01, 0.17)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Metabolism and nutrition disorders						
Hyponatraemia	3 (4.5%)	1 (2.6%)	4 (3.8%)	2 (4.7%)	3 (10.0%)	5 (6.8%)
Unadjusted Relative Risk (95% CI)	1.77 (0.19, 16.46)					
p-value [1]	0.61					
Unadjusted Odds Ratio (95% CI)	1.81 (0.18, 18.03)					
p-value [1]	0.61					
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.05, 0.09)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.0901: TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Metabolism and nutrition disorders						
Hypokalaemia	2 (3.0%)	0	2 (1.9%)	3 (7.0%)	3 (10.0%)	6 (8.2%)
Unadjusted Relative Risk (95% CI)	2.99 (0.15, 60.62)					
p-value [1]	0.48					
Unadjusted Odds Ratio (95% CI)	3.06 (0.14, 65.44)					
p-value [1]	0.47					
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.03, 0.08)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Respiratory, thoracic and mediastinal disorders						
Any Event	24 (36.4%)	13 (33.3%)	37 (35.2%)	24 (55.8%)	15 (50.0%)	39 (53.4%)
Unadjusted Relative Risk (95% CI)	1.09 (0.63, 1.88)					
p-value [1]	0.76					
Unadjusted Odds Ratio (95% CI)	1.14 (0.50, 2.63)					
p-value [1]	0.75					
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.16, 0.22)					
Adjusted Relative Risk (95% CI) [2]	1.09 (0.63, 1.87)					
p-value [2]	0.76					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.0901: TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Respiratory, thoracic and mediastinal disorders						
Cough	9 (13.6%)	4 (10.3%)	13 (12.4%)	13 (30.2%)	6 (20.0%)	19 (26.0%)
Unadjusted Relative Risk (95% CI)	1.33 (0.44, 4.03)					
p-value [1]	0.61					
Unadjusted Odds Ratio (95% CI)	1.38 (0.40, 4.83)					
p-value [1]	0.61					
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.09, 0.16)					
Adjusted Relative Risk (95% CI) [2]	1.32 (0.47, 3.73)					
p-value [2]	0.60					
Respiratory, thoracic and mediastinal disorders						
Dyspnoea	8 (12.1%)	6 (15.4%)	14 (13.3%)	4 (9.3%)	6 (20.0%)	10 (13.7%)
Unadjusted Relative Risk (95% CI)	0.79 (0.30, 2.10)					
p-value [1]	0.63					
Unadjusted Odds Ratio (95% CI)	0.76 (0.24, 2.38)					
p-value [1]	0.64					
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.17, 0.11)					
Adjusted Relative Risk (95% CI) [2]	0.88 (0.35, 2.25)					
p-value [2]	0.79					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.0901: TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Respiratory, thoracic and mediastinal disorders						
Epistaxis	6 (9.1%)	5 (12.8%)	11 (10.5%)	1 (2.3%)	2 (6.7%)	3 (4.1%)
Unadjusted Relative Risk (95% CI)	0.71 (0.23, 2.17)					
p-value [1]	0.55					
Unadjusted Odds Ratio (95% CI)	0.68 (0.19, 2.40)					
p-value [1]	0.55					
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.16, 0.09)					
Adjusted Relative Risk (95% CI) [2]	0.71 (0.22, 2.28)					
p-value [2]	0.56					
Skin and subcutaneous tissue disorders						
Any Event	22 (33.3%)	11 (28.2%)	33 (31.4%)	13 (30.2%)	10 (33.3%)	23 (31.5%)
Unadjusted Relative Risk (95% CI)	1.18 (0.64, 2.17)					
p-value [1]	0.59					
Unadjusted Odds Ratio (95% CI)	1.27 (0.54, 3.02)					
p-value [1]	0.58					
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.13, 0.23)					
Adjusted Relative Risk (95% CI) [2]	1.22 (0.67, 2.23)					
p-value [2]	0.52					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.0901: TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Skin and subcutaneous tissue disorders						
Pruritus	10 (15.2%)	3 (7.7%)	13 (12.4%)	4 (9.3%)	2 (6.7%)	6 (8.2%)
Unadjusted Relative Risk (95% CI)	1.97 (0.58, 6.73)					
p-value [1]	0.28					
Unadjusted Odds Ratio (95% CI)	2.14 (0.55, 8.32)					
p-value [1]	0.27					
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.05, 0.19)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Skin and subcutaneous tissue disorders						
Night sweats	5 (7.6%)	2 (5.1%)	7 (6.7%)	2 (4.7%)	4 (13.3%)	6 (8.2%)
Unadjusted Relative Risk (95% CI)	1.48 (0.30, 7.25)					
p-value [1]	0.63					
Unadjusted Odds Ratio (95% CI)	1.52 (0.28, 8.22)					
p-value [1]	0.63					
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.07, 0.12)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.0901: TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC PT	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
Skin and subcutaneous tissue disorders						
Hyperhidrosis	2 (3.0%)	4 (10.3%)	6 (5.7%)	1 (2.3%)	2 (6.7%)	3 (4.1%)
Unadjusted Relative Risk (95% CI)	0.30 (0.06, 1.54)					
p-value [1]	0.15					
Unadjusted Odds Ratio (95% CI)	0.27 (0.05, 1.57)					
p-value [1]	0.15					
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.18, 0.03)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Musculoskeletal and connective tissue disorders						
Any Event	21 (31.8%)	14 (35.9%)	35 (33.3%)	18 (41.9%)	11 (36.7%)	29 (39.7%)
Unadjusted Relative Risk (95% CI)	0.89 (0.51, 1.53)					
p-value [1]	0.67					
Unadjusted Odds Ratio (95% CI)	0.83 (0.36, 1.92)					
p-value [1]	0.67					
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.23, 0.15)					
Adjusted Relative Risk (95% CI) [2]	0.96 (0.55, 1.68)					
p-value [2]	0.89					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.0901: TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Musculoskeletal and connective tissue disorders						
Arthralgia	8 (12.1%)	3 (7.7%)	11 (10.5%)	3 (7.0%)	0	3 (4.1%)
Unadjusted Relative Risk (95% CI)	1.58 (0.44, 5.59)					
p-value [1]	0.48					
Unadjusted Odds Ratio (95% CI)	1.66 (0.41, 6.65)					
p-value [1]	0.48					
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.07, 0.16)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Musculoskeletal and connective tissue disorders						
Pain in extremity	3 (4.5%)	4 (10.3%)	7 (6.7%)	6 (14.0%)	1 (3.3%)	7 (9.6%)
Unadjusted Relative Risk (95% CI)	0.44 (0.10, 1.88)					
p-value [1]	0.27					
Unadjusted Odds Ratio (95% CI)	0.42 (0.09, 1.97)					
p-value [1]	0.27					
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.16, 0.05)					
Adjusted Relative Risk (95% CI) [2]	0.51 (0.10, 2.52)					
p-value [2]	0.41					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.0901: TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Musculoskeletal and connective tissue disorders						
Back pain	2 (3.0%)	2 (5.1%)	4 (3.8%)	5 (11.6%)	1 (3.3%)	6 (8.2%)
Unadjusted Relative Risk (95% CI)	0.59 (0.09, 4.03)					
p-value [1]	0.59					
Unadjusted Odds Ratio (95% CI)	0.58 (0.08, 4.28)					
p-value [1]	0.59					
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.10, 0.06)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Musculoskeletal and connective tissue disorders						
Bone pain	2 (3.0%)	4 (10.3%)	6 (5.7%)	1 (2.3%)	3 (10.0%)	4 (5.5%)
Unadjusted Relative Risk (95% CI)	0.30 (0.06, 1.54)					
p-value [1]	0.15					
Unadjusted Odds Ratio (95% CI)	0.27 (0.05, 1.57)					
p-value [1]	0.15					
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.18, 0.03)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.0901: TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Investigations						
Any Event	17 (25.8%)	3 (7.7%)	20 (19.0%)	18 (41.9%)	9 (30.0%)	27 (37.0%)
Unadjusted Relative Risk (95% CI)	3.35 (1.05, 10.70)					
p-value [1]	0.041					
Unadjusted Odds Ratio (95% CI)	4.16 (1.13, 15.29)					
p-value [1]	0.032					
Unadjusted Absolute Risk Difference (95% CI)	0.18 (0.05, 0.32)					
Adjusted Relative Risk (95% CI) [2]	3.14 (0.95, 10.34)					
p-value [2]	0.060					
Investigations						
Weight decreased	7 (10.6%)	1 (2.6%)	8 (7.6%)	4 (9.3%)	4 (13.3%)	8 (11.0%)
Unadjusted Relative Risk (95% CI)	4.14 (0.53, 32.38)					
p-value [1]	0.18					
Unadjusted Odds Ratio (95% CI)	4.51 (0.53, 38.11)					
p-value [1]	0.17					
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.01, 0.17)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.0901: TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Vascular disorders						
Any Event	9 (13.6%)	2 (5.1%)	11 (10.5%)	10 (23.3%)	7 (23.3%)	17 (23.3%)
Unadjusted Relative Risk (95% CI)	2.66 (0.61, 11.68)					
p-value [1]	0.20					
Unadjusted Odds Ratio (95% CI)	2.92 (0.60, 14.28)					
p-value [1]	0.19					
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.02, 0.19)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Cardiac disorders						
Any Event	8 (12.1%)	5 (12.8%)	13 (12.4%)	8 (18.6%)	7 (23.3%)	15 (20.5%)
Unadjusted Relative Risk (95% CI)	0.95 (0.33, 2.69)					
p-value [1]	0.92					
Unadjusted Odds Ratio (95% CI)	0.94 (0.28, 3.10)					
p-value [1]	0.92					
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.14, 0.12)					
Adjusted Relative Risk (95% CI) [2]	0.97 (0.38, 2.51)					
p-value [2]	0.96					

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Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.0901: TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Psychiatric disorders						
Any Event	8 (12.1%)	5 (12.8%)	13 (12.4%)	10 (23.3%)	7 (23.3%)	17 (23.3%)
Unadjusted Relative Risk (95% CI)	0.95 (0.33, 2.69)					
p-value [1]	0.92					
Unadjusted Odds Ratio (95% CI)	0.94 (0.28, 3.10)					
p-value [1]	0.92					
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.14, 0.12)					
Adjusted Relative Risk (95% CI) [2]	1.01 (0.36, 2.87)					
p-value [2]	0.99					
Psychiatric disorders						
Insomnia	2 (3.0%)	3 (7.7%)	5 (4.8%)	4 (9.3%)	3 (10.0%)	7 (9.6%)
Unadjusted Relative Risk (95% CI)	0.39 (0.07, 2.26)					
p-value [1]	0.30					
Unadjusted Odds Ratio (95% CI)	0.38 (0.06, 2.35)					
p-value [1]	0.29					
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.14, 0.05)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.0901: TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Eye disorders						
Any Event	7 (10.6%)	4 (10.3%)	11 (10.5%)	4 (9.3%)	5 (16.7%)	9 (12.3%)
Unadjusted Relative Risk (95% CI)	1.03 (0.32, 3.31)					
p-value [1]	0.95					
Unadjusted Odds Ratio (95% CI)	1.04 (0.28, 3.80)					
p-value [1]	0.95					
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.12, 0.12)					
Adjusted Relative Risk (95% CI) [2]	1.04 (0.34, 3.16)					
p-value [2]	0.94					
Injury, poisoning and procedural complications						
Any Event	7 (10.6%)	4 (10.3%)	11 (10.5%)	7 (16.3%)	3 (10.0%)	10 (13.7%)
Unadjusted Relative Risk (95% CI)	1.03 (0.32, 3.31)					
p-value [1]	0.95					
Unadjusted Odds Ratio (95% CI)	1.04 (0.28, 3.80)					
p-value [1]	0.95					
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.12, 0.12)					
Adjusted Relative Risk (95% CI) [2]	1.00 (0.35, 2.87)					
p-value [2]	1.00					

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Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.0901: TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC PT	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event	7 (10.6%)	4 (10.3%)	11 (10.5%)	9 (20.9%)	3 (10.0%)	12 (16.4%)
Unadjusted Relative Risk (95% CI)	1.03 (0.32, 3.31)					
p-value [1]	0.95					
Unadjusted Odds Ratio (95% CI)	1.04 (0.28, 3.80)					
p-value [1]	0.95					
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.12, 0.12)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Renal and urinary disorders						
Any Event	5 (7.6%)	3 (7.7%)	8 (7.6%)	15 (34.9%)	11 (36.7%)	26 (35.6%)
Unadjusted Relative Risk (95% CI)	0.98 (0.25, 3.90)					
p-value [1]	0.98					
Unadjusted Odds Ratio (95% CI)	0.98 (0.22, 4.36)					
p-value [1]	0.98					
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.11, 0.10)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.0901: TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Renal and urinary disorders						
Acute kidney injury	1 (1.5%)	0	1 (1.0%)	4 (9.3%)	4 (13.3%)	8 (11.0%)
Unadjusted Relative Risk (95% CI)	1.79 (0.07, 42.92)					
p-value [1]	0.72					
Unadjusted Odds Ratio (95% CI)	1.81 (0.07, 45.50)					
p-value [1]	0.72					
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.04, 0.06)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

2.10.3 UE nach Schweregrad

GSK Oncology
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Table 3.1201: TEAEs of Grade 3 or more by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Any TEAE of Grade 3 or more						
Number of Subjects With Any Event	40 (60.6%)	18 (46.2%)	58 (55.2%)	31 (72.1%)	22 (73.3%)	53 (72.6%)
Unadjusted Relative Risk (95% CI)	1.31 (0.89, 1.94)					
p-value [1]	0.17					
Unadjusted Odds Ratio (95% CI)	1.79 (0.81, 3.99)					
p-value [1]	0.15					
Unadjusted Absolute Risk Difference (95% CI)	0.14 (-0.05, 0.34)					
Adjusted Relative Risk (95% CI) [2]	1.35 (0.91, 1.98)					
p-value [2]	0.13					
Blood and lymphatic system disorders						
Any Event	18 (27.3%)	12 (30.8%)	30 (28.6%)	14 (32.6%)	14 (46.7%)	28 (38.4%)
Unadjusted Relative Risk (95% CI)	0.89 (0.48, 1.64)					
p-value [1]	0.70					
Unadjusted Odds Ratio (95% CI)	0.84 (0.35, 2.01)					
p-value [1]	0.70					
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.22, 0.15)					
Adjusted Relative Risk (95% CI) [2]	0.89 (0.48, 1.65)					
p-value [2]	0.72					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1201: TEAEs of Grade 3 or more by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Blood and lymphatic system disorders						
Anaemia	12 (18.2%)	9 (23.1%)	21 (20.0%)	10 (23.3%)	8 (26.7%)	18 (24.7%)
Unadjusted Relative Risk (95% CI)	0.79 (0.37, 1.70)					
p-value [1]	0.54					
Unadjusted Odds Ratio (95% CI)	0.74 (0.28, 1.96)					
p-value [1]	0.55					
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.21, 0.11)					
Adjusted Relative Risk (95% CI) [2]	0.81 (0.39, 1.68)					
p-value [2]	0.57					
Blood and lymphatic system disorders						
Thrombocytopenia	6 (9.1%)	2 (5.1%)	8 (7.6%)	4 (9.3%)	5 (16.7%)	9 (12.3%)
Unadjusted Relative Risk (95% CI)	1.77 (0.38, 8.36)					
p-value [1]	0.47					
Unadjusted Odds Ratio (95% CI)	1.85 (0.35, 9.65)					
p-value [1]	0.47					
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.06, 0.14)					
Adjusted Relative Risk (95% CI) [2]	1.66 (0.30, 9.21)					
p-value [2]	0.56					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1201: TEAEs of Grade 3 or more by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Blood and lymphatic system disorders						
Neutropenia	5 (7.6%)	1 (2.6%)	6 (5.7%)	2 (4.7%)	2 (6.7%)	4 (5.5%)
Unadjusted Relative Risk (95% CI)	2.95 (0.36, 24.38)					
p-value [1]	0.31					
Unadjusted Odds Ratio (95% CI)	3.11 (0.35, 27.69)					
p-value [1]	0.31					
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.03, 0.13)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Blood and lymphatic system disorders						
Splenic infarction	0	0	0	0	2 (6.7%)	2 (2.7%)
Unadjusted Relative Risk (95% CI)	NE					
p-value [1]	NE					
Unadjusted Odds Ratio (95% CI)	NE					
p-value [1]	NE					
Unadjusted Absolute Risk Difference (95% CI)	NE					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1201: TEAEs of Grade 3 or more by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Infections and infestations						
Any Event	9 (13.6%)	4 (10.3%)	13 (12.4%)	12 (27.9%)	4 (13.3%)	16 (21.9%)
Unadjusted Relative Risk (95% CI)	1.33 (0.44, 4.03)					
p-value [1]	0.61					
Unadjusted Odds Ratio (95% CI)	1.38 (0.40, 4.83)					
p-value [1]	0.61					
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.09, 0.16)					
Adjusted Relative Risk (95% CI) [2]	1.32 (0.43, 4.07)					
p-value [2]	0.63					
Infections and infestations						
Sepsis	3 (4.5%)	2 (5.1%)	5 (4.8%)	4 (9.3%)	1 (3.3%)	5 (6.8%)
Unadjusted Relative Risk (95% CI)	0.89 (0.15, 5.07)					
p-value [1]	0.89					
Unadjusted Odds Ratio (95% CI)	0.88 (0.14, 5.52)					
p-value [1]	0.89					
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.09, 0.08)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1201: TEAEs of Grade 3 or more by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Infections and infestations						
Pneumonia	2 (3.0%)	1 (2.6%)	3 (2.9%)	5 (11.6%)	2 (6.7%)	7 (9.6%)
Unadjusted Relative Risk (95% CI)	1.18 (0.11, 12.61)					
p-value [1]	0.89					
Unadjusted Odds Ratio (95% CI)	1.19 (0.10, 13.54)					
p-value [1]	0.89					
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.06, 0.07)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
General disorders and administration site conditions						
Any Event	8 (12.1%)	1 (2.6%)	9 (8.6%)	5 (11.6%)	4 (13.3%)	9 (12.3%)
Unadjusted Relative Risk (95% CI)	4.73 (0.61, 36.39)					
p-value [1]	0.14					
Unadjusted Odds Ratio (95% CI)	5.24 (0.63, 43.61)					
p-value [1]	0.13					
Unadjusted Absolute Risk Difference (95% CI)	0.10 (0.00, 0.19)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1201: TEAEs of Grade 3 or more by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
General disorders and administration site conditions						
Asthenia	4 (6.1%)	1 (2.6%)	5 (4.8%)	1 (2.3%)	3 (10.0%)	4 (5.5%)
Unadjusted Relative Risk (95% CI)	2.36 (0.27, 20.40)					
p-value [1]	0.43					
Unadjusted Odds Ratio (95% CI)	2.45 (0.26, 22.76)					
p-value [1]	0.43					
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.04, 0.11)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Cardiac disorders						
Any Event	6 (9.1%)	2 (5.1%)	8 (7.6%)	5 (11.6%)	2 (6.7%)	7 (9.6%)
Unadjusted Relative Risk (95% CI)	1.77 (0.38, 8.36)					
p-value [1]	0.47					
Unadjusted Odds Ratio (95% CI)	1.85 (0.35, 9.65)					
p-value [1]	0.47					
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.06, 0.14)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1201: TEAEs of Grade 3 or more by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Gastrointestinal disorders						
Any Event	5 (7.6%)	3 (7.7%)	8 (7.6%)	3 (7.0%)	6 (20.0%)	9 (12.3%)
Unadjusted Relative Risk (95% CI)	0.98 (0.25, 3.90)					
p-value [1]	0.98					
Unadjusted Odds Ratio (95% CI)	0.98 (0.22, 4.36)					
p-value [1]	0.98					
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.11, 0.10)					
Adjusted Relative Risk (95% CI) [2]	1.00 (0.29, 3.47)					
p-value [2]	0.99					
Gastrointestinal disorders						
Abdominal pain	1 (1.5%)	3 (7.7%)	4 (3.8%)	1 (2.3%)	0	1 (1.4%)
Unadjusted Relative Risk (95% CI)	0.20 (0.02, 1.83)					
p-value [1]	0.15					
Unadjusted Odds Ratio (95% CI)	0.18 (0.02, 1.84)					
p-value [1]	0.15					
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.15, 0.03)					
Adjusted Relative Risk (95% CI) [2]	0.23 (0.03, 1.63)					
p-value [2]	0.14					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1201: TEAEs of Grade 3 or more by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Gastrointestinal disorders						
Diarrhoea	1 (1.5%)	0	1 (1.0%)	1 (2.3%)	2 (6.7%)	3 (4.1%)
Unadjusted Relative Risk (95% CI)	1.79 (0.07, 42.92)					
p-value [1]	0.72					
Unadjusted Odds Ratio (95% CI)	1.81 (0.07, 45.50)					
p-value [1]	0.72					
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.04, 0.06)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Metabolism and nutrition disorders						
Any Event	5 (7.6%)	4 (10.3%)	9 (8.6%)	4 (9.3%)	3 (10.0%)	7 (9.6%)
Unadjusted Relative Risk (95% CI)	0.74 (0.21, 2.59)					
p-value [1]	0.64					
Unadjusted Odds Ratio (95% CI)	0.72 (0.18, 2.85)					
p-value [1]	0.64					
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.14, 0.09)					
Adjusted Relative Risk (95% CI) [2]	0.81 (0.21, 3.20)					
p-value [2]	0.77					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1201: TEAEs of Grade 3 or more by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Metabolism and nutrition disorders						
Hyponatraemia	0	0	0	0	2 (6.7%)	2 (2.7%)
Unadjusted Relative Risk (95% CI)	NE					
p-value [1]	NE					
Unadjusted Odds Ratio (95% CI)	NE					
p-value [1]	NE					
Unadjusted Absolute Risk Difference (95% CI)	NE					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Metabolism and nutrition disorders						
Iron overload	0	2 (5.1%)	2 (1.9%)	0	0	0
Unadjusted Relative Risk (95% CI)	0.12 (0.01, 2.42)					
p-value [1]	0.17					
Unadjusted Odds Ratio (95% CI)	0.11 (0.01, 2.41)					
p-value [1]	0.16					
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.13, 0.02)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1201: TEAEs of Grade 3 or more by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Respiratory, thoracic and mediastinal disorders						
Any Event	5 (7.6%)	1 (2.6%)	6 (5.7%)	10 (23.3%)	6 (20.0%)	16 (21.9%)
Unadjusted Relative Risk (95% CI)	2.95 (0.36, 24.38)					
p-value [1]	0.31					
Unadjusted Odds Ratio (95% CI)	3.11 (0.35, 27.69)					
p-value [1]	0.31					
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.03, 0.13)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Respiratory, thoracic and mediastinal disorders						
Pulmonary oedema	0	0	0	0	2 (6.7%)	2 (2.7%)
Unadjusted Relative Risk (95% CI)	NE					
p-value [1]	NE					
Unadjusted Odds Ratio (95% CI)	NE					
p-value [1]	NE					
Unadjusted Absolute Risk Difference (95% CI)	NE					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1201: TEAEs of Grade 3 or more by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Vascular disorders						
Any Event	3 (4.5%)	1 (2.6%)	4 (3.8%)	3 (7.0%)	1 (3.3%)	4 (5.5%)
Unadjusted Relative Risk (95% CI)	1.77 (0.19, 16.46)					
p-value [1]	0.61					
Unadjusted Odds Ratio (95% CI)	1.81 (0.18, 18.03)					
p-value [1]	0.61					
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.05, 0.09)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Investigations						
Any Event	2 (3.0%)	0	2 (1.9%)	4 (9.3%)	2 (6.7%)	6 (8.2%)
Unadjusted Relative Risk (95% CI)	2.99 (0.15, 60.62)					
p-value [1]	0.48					
Unadjusted Odds Ratio (95% CI)	3.06 (0.14, 65.44)					
p-value [1]	0.47					
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.03, 0.08)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1201: TEAEs of Grade 3 or more by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event	2 (3.0%)	3 (7.7%)	5 (4.8%)	5 (11.6%)	1 (3.3%)	6 (8.2%)
Unadjusted Relative Risk (95% CI)	0.39 (0.07, 2.26)					
p-value [1]	0.30					
Unadjusted Odds Ratio (95% CI)	0.38 (0.06, 2.35)					
p-value [1]	0.29					
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.14, 0.05)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Nervous system disorders						
Any Event	2 (3.0%)	1 (2.6%)	3 (2.9%)	5 (11.6%)	2 (6.7%)	7 (9.6%)
Unadjusted Relative Risk (95% CI)	1.18 (0.11, 12.61)					
p-value [1]	0.89					
Unadjusted Odds Ratio (95% CI)	1.19 (0.10, 13.54)					
p-value [1]	0.89					
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.06, 0.07)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1201: TEAEs of Grade 3 or more by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Injury, poisoning and procedural complications						
Any Event	1 (1.5%)	0	1 (1.0%)	3 (7.0%)	0	3 (4.1%)
Unadjusted Relative Risk (95% CI)	1.79 (0.07, 42.92)					
p-value [1]	0.72					
Unadjusted Odds Ratio (95% CI)	1.81 (0.07, 45.50)					
p-value [1]	0.72					
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.04, 0.06)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Renal and urinary disorders						
Any Event	1 (1.5%)	1 (2.6%)	2 (1.9%)	5 (11.6%)	2 (6.7%)	7 (9.6%)
Unadjusted Relative Risk (95% CI)	0.59 (0.04, 9.18)					
p-value [1]	0.71					
Unadjusted Odds Ratio (95% CI)	0.58 (0.04, 9.62)					
p-value [1]	0.71					
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.07, 0.05)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1201: TEAEs of Grade 3 or more by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC PT	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
Skin and subcutaneous tissue disorders						
Any Event	0	1 (2.6%)	1 (1.0%)	1 (2.3%)	2 (6.7%)	3 (4.1%)
Unadjusted Relative Risk (95% CI)	0.20 (0.01, 4.77)					
p-value [1]	0.32					
Unadjusted Odds Ratio (95% CI)	0.19 (0.01, 4.86)					
p-value [1]	0.32					
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.09, 0.03)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1001: TEAEs of Grade 2 or less by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Any TEAE of Grade 2 or less						
Number of Subjects With Any Event	64 (97.0%)	34 (87.2%)	98 (93.3%)	42 (97.7%)	29 (96.7%)	71 (97.3%)
Unadjusted Relative Risk (95% CI)	1.11 (0.98, 1.26)					
p-value [1]	0.10					
Unadjusted Odds Ratio (95% CI)	4.71 (0.87, 25.55)					
p-value [1]	0.073					
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.01, 0.21)					
Adjusted Relative Risk (95% CI) [2]	1.11 (0.97, 1.26)					
p-value [2]	0.13					
Gastrointestinal disorders						
Any Event	39 (59.1%)	16 (41.0%)	55 (52.4%)	19 (44.2%)	20 (66.7%)	39 (53.4%)
Unadjusted Relative Risk (95% CI)	1.44 (0.94, 2.21)					
p-value [1]	0.094					
Unadjusted Odds Ratio (95% CI)	2.08 (0.93, 4.64)					
p-value [1]	0.075					
Unadjusted Absolute Risk Difference (95% CI)	0.18 (-0.01, 0.38)					
Adjusted Relative Risk (95% CI) [2]	1.50 (0.98, 2.30)					
p-value [2]	0.061					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1001: TEAEs of Grade 2 or less by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Gastrointestinal disorders						
Diarrhoea	20 (30.3%)	5 (12.8%)	25 (23.8%)	12 (27.9%)	6 (20.0%)	18 (24.7%)
Unadjusted Relative Risk (95% CI)	2.36 (0.96, 5.79)					
p-value [1]	0.060					
Unadjusted Odds Ratio (95% CI)	2.96 (1.01, 8.67)					
p-value [1]	0.048					
Unadjusted Absolute Risk Difference (95% CI)	0.17 (0.02, 0.33)					
Adjusted Relative Risk (95% CI) [2]	2.09 (0.84, 5.18)					
p-value [2]	0.11					
Gastrointestinal disorders						
Nausea	12 (18.2%)	2 (5.1%)	14 (13.3%)	5 (11.6%)	5 (16.7%)	10 (13.7%)
Unadjusted Relative Risk (95% CI)	3.55 (0.84, 15.02)					
p-value [1]	0.086					
Unadjusted Odds Ratio (95% CI)	4.11 (0.87, 19.45)					
p-value [1]	0.075					
Unadjusted Absolute Risk Difference (95% CI)	0.13 (0.01, 0.25)					
Adjusted Relative Risk (95% CI) [2]	4.37 (1.13, 16.87)					
p-value [2]	0.032					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1001: TEAEs of Grade 2 or less by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Gastrointestinal disorders						
Abdominal pain	9 (13.6%)	3 (7.7%)	12 (11.4%)	3 (7.0%)	3 (10.0%)	6 (8.2%)
Unadjusted Relative Risk (95% CI)	1.77 (0.51, 6.16)					
p-value [1]	0.37					
Unadjusted Odds Ratio (95% CI)	1.89 (0.48, 7.47)					
p-value [1]	0.36					
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.06, 0.18)					
Adjusted Relative Risk (95% CI) [2]	2.03 (0.60, 6.90)					
p-value [2]	0.26					
Gastrointestinal disorders						
Dyspepsia	7 (10.6%)	0	7 (6.7%)	1 (2.3%)	1 (3.3%)	2 (2.7%)
Unadjusted Relative Risk (95% CI)	8.96 (0.53, 152.64)					
p-value [1]	0.13					
Unadjusted Odds Ratio (95% CI)	9.96 (0.55, 179.34)					
p-value [1]	0.12					
Unadjusted Absolute Risk Difference (95% CI)	0.10 (0.02, 0.18)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1001: TEAEs of Grade 2 or less by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Gastrointestinal disorders						
Abdominal pain upper	4 (6.1%)	1 (2.6%)	5 (4.8%)	1 (2.3%)	3 (10.0%)	4 (5.5%)
Unadjusted Relative Risk (95% CI)	2.36 (0.27, 20.40)					
p-value [1]	0.43					
Unadjusted Odds Ratio (95% CI)	2.45 (0.26, 22.76)					
p-value [1]	0.43					
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.04, 0.11)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
General disorders and administration site conditions						
Any Event	32 (48.5%)	20 (51.3%)	52 (49.5%)	25 (58.1%)	16 (53.3%)	41 (56.2%)
Unadjusted Relative Risk (95% CI)	0.95 (0.64, 1.40)					
p-value [1]	0.78					
Unadjusted Odds Ratio (95% CI)	0.89 (0.40, 1.97)					
p-value [1]	0.78					
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.23, 0.17)					
Adjusted Relative Risk (95% CI) [2]	0.96 (0.65, 1.43)					
p-value [2]	0.85					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1001: TEAEs of Grade 2 or less by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
General disorders and administration site conditions						
Asthenia	11 (16.7%)	8 (20.5%)	19 (18.1%)	6 (14.0%)	7 (23.3%)	13 (17.8%)
Unadjusted Relative Risk (95% CI)	0.81 (0.36, 1.85)					
p-value [1]	0.62					
Unadjusted Odds Ratio (95% CI)	0.78 (0.28, 2.13)					
p-value [1]	0.62					
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.19, 0.12)					
Adjusted Relative Risk (95% CI) [2]	0.85 (0.38, 1.88)					
p-value [2]	0.68					
General disorders and administration site conditions						
Fatigue	10 (15.2%)	7 (17.9%)	17 (16.2%)	3 (7.0%)	4 (13.3%)	7 (9.6%)
Unadjusted Relative Risk (95% CI)	0.84 (0.35, 2.04)					
p-value [1]	0.71					
Unadjusted Odds Ratio (95% CI)	0.82 (0.28, 2.35)					
p-value [1]	0.71					
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.18, 0.12)					
Adjusted Relative Risk (95% CI) [2]	0.93 (0.38, 2.30)					
p-value [2]	0.88					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1001: TEAEs of Grade 2 or less by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
General disorders and administration site conditions						
Pyrexia	10 (15.2%)	3 (7.7%)	13 (12.4%)	11 (25.6%)	9 (30.0%)	20 (27.4%)
Unadjusted Relative Risk (95% CI)	1.97 (0.58, 6.73)					
p-value [1]	0.28					
Unadjusted Odds Ratio (95% CI)	2.14 (0.55, 8.32)					
p-value [1]	0.27					
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.05, 0.19)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
General disorders and administration site conditions						
Oedema peripheral	8 (12.1%)	5 (12.8%)	13 (12.4%)	8 (18.6%)	2 (6.7%)	10 (13.7%)
Unadjusted Relative Risk (95% CI)	0.95 (0.33, 2.69)					
p-value [1]	0.92					
Unadjusted Odds Ratio (95% CI)	0.94 (0.28, 3.10)					
p-value [1]	0.92					
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.14, 0.12)					
Adjusted Relative Risk (95% CI) [2]	1.02 (0.36, 2.92)					
p-value [2]	0.97					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1001: TEAEs of Grade 2 or less by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
General disorders and administration site conditions						
Early satiety	2 (3.0%)	4 (10.3%)	6 (5.7%)	1 (2.3%)	1 (3.3%)	2 (2.7%)
Unadjusted Relative Risk (95% CI)	0.30 (0.06, 1.54)					
p-value [1]	0.15					
Unadjusted Odds Ratio (95% CI)	0.27 (0.05, 1.57)					
p-value [1]	0.15					
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.18, 0.03)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Nervous system disorders						
Any Event	32 (48.5%)	7 (17.9%)	39 (37.1%)	18 (41.9%)	16 (53.3%)	34 (46.6%)
Unadjusted Relative Risk (95% CI)	2.70 (1.32, 5.53)					
p-value [1]	0.006					
Unadjusted Odds Ratio (95% CI)	4.30 (1.66, 11.12)					
p-value [1]	0.003					
Unadjusted Absolute Risk Difference (95% CI)	0.31 (0.13, 0.48)					
Adjusted Relative Risk (95% CI) [2]	2.71 (1.32, 5.58)					
p-value [2]	0.007					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1001: TEAEs of Grade 2 or less by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Nervous system disorders						
Dizziness	11 (16.7%)	3 (7.7%)	14 (13.3%)	6 (14.0%)	3 (10.0%)	9 (12.3%)
Unadjusted Relative Risk (95% CI)	2.17 (0.64, 7.29)					
p-value [1]	0.21					
Unadjusted Odds Ratio (95% CI)	2.40 (0.63, 9.20)					
p-value [1]	0.20					
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.03, 0.21)					
Adjusted Relative Risk (95% CI) [2]	1.98 (0.59, 6.68)					
p-value [2]	0.27					
Nervous system disorders						
Headache	8 (12.1%)	2 (5.1%)	10 (9.5%)	0	5 (16.7%)	5 (6.8%)
Unadjusted Relative Risk (95% CI)	2.36 (0.53, 10.57)					
p-value [1]	0.26					
Unadjusted Odds Ratio (95% CI)	2.55 (0.51, 12.68)					
p-value [1]	0.25					
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.03, 0.17)					
Adjusted Relative Risk (95% CI) [2]	2.30 (0.50, 10.69)					
p-value [2]	0.29					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1001: TEAEs of Grade 2 or less by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Nervous system disorders						
Peripheral sensory neuropathy	6 (9.1%)	0	6 (5.7%)	4 (9.3%)	6 (20.0%)	10 (13.7%)
Unadjusted Relative Risk (95% CI)	7.76 (0.45, 134.13)					
p-value [1]	0.16					
Unadjusted Odds Ratio (95% CI)	8.49 (0.47, 154.92)					
p-value [1]	0.15					
Unadjusted Absolute Risk Difference (95% CI)	0.08 (0.01, 0.16)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Nervous system disorders						
Paraesthesia	4 (6.1%)	1 (2.6%)	5 (4.8%)	1 (2.3%)	3 (10.0%)	4 (5.5%)
Unadjusted Relative Risk (95% CI)	2.36 (0.27, 20.40)					
p-value [1]	0.43					
Unadjusted Odds Ratio (95% CI)	2.45 (0.26, 22.76)					
p-value [1]	0.43					
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.04, 0.11)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1001: TEAEs of Grade 2 or less by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Infections and infestations						
Any Event	30 (45.5%)	14 (35.9%)	44 (41.9%)	24 (55.8%)	18 (60.0%)	42 (57.5%)
Unadjusted Relative Risk (95% CI)	1.27 (0.77, 2.08)					
p-value [1]	0.35					
Unadjusted Odds Ratio (95% CI)	1.49 (0.66, 3.36)					
p-value [1]	0.34					
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.10, 0.29)					
Adjusted Relative Risk (95% CI) [2]	1.26 (0.76, 2.08)					
p-value [2]	0.36					
Infections and infestations						
Upper respiratory tract infection	7 (10.6%)	3 (7.7%)	10 (9.5%)	7 (16.3%)	5 (16.7%)	12 (16.4%)
Unadjusted Relative Risk (95% CI)	1.38 (0.38, 5.03)					
p-value [1]	0.63					
Unadjusted Odds Ratio (95% CI)	1.42 (0.35, 5.86)					
p-value [1]	0.62					
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.08, 0.14)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1001: TEAEs of Grade 2 or less by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Infections and infestations						
Urinary tract infection	5 (7.6%)	3 (7.7%)	8 (7.6%)	6 (14.0%)	6 (20.0%)	12 (16.4%)
Unadjusted Relative Risk (95% CI)	0.98 (0.25, 3.90)					
p-value [1]	0.98					
Unadjusted Odds Ratio (95% CI)	0.98 (0.22, 4.36)					
p-value [1]	0.98					
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.11, 0.10)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Infections and infestations						
Bronchitis	2 (3.0%)	0	2 (1.9%)	6 (14.0%)	3 (10.0%)	9 (12.3%)
Unadjusted Relative Risk (95% CI)	2.99 (0.15, 60.62)					
p-value [1]	0.48					
Unadjusted Odds Ratio (95% CI)	3.06 (0.14, 65.44)					
p-value [1]	0.47					
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.03, 0.08)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1001: TEAEs of Grade 2 or less by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Metabolism and nutrition disorders						
Any Event	23 (34.8%)	6 (15.4%)	29 (27.6%)	19 (44.2%)	9 (30.0%)	28 (38.4%)
Unadjusted Relative Risk (95% CI)	2.27 (1.01, 5.07)					
p-value [1]	0.047					
Unadjusted Odds Ratio (95% CI)	2.94 (1.08, 8.05)					
p-value [1]	0.036					
Unadjusted Absolute Risk Difference (95% CI)	0.19 (0.03, 0.36)					
Adjusted Relative Risk (95% CI) [2]	2.32 (1.02, 5.27)					
p-value [2]	0.044					
Metabolism and nutrition disorders						
Vitamin B1 deficiency	7 (10.6%)	1 (2.6%)	8 (7.6%)	5 (11.6%)	1 (3.3%)	6 (8.2%)
Unadjusted Relative Risk (95% CI)	4.14 (0.53, 32.38)					
p-value [1]	0.18					
Unadjusted Odds Ratio (95% CI)	4.51 (0.53, 38.11)					
p-value [1]	0.17					
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.01, 0.17)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1001: TEAEs of Grade 2 or less by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Skin and subcutaneous tissue disorders						
Any Event	22 (33.3%)	11 (28.2%)	33 (31.4%)	13 (30.2%)	10 (33.3%)	23 (31.5%)
Unadjusted Relative Risk (95% CI)	1.18 (0.64, 2.17)					
p-value [1]	0.59					
Unadjusted Odds Ratio (95% CI)	1.27 (0.54, 3.02)					
p-value [1]	0.58					
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.13, 0.23)					
Adjusted Relative Risk (95% CI) [2]	1.22 (0.67, 2.23)					
p-value [2]	0.52					
Skin and subcutaneous tissue disorders						
Pruritus	10 (15.2%)	3 (7.7%)	13 (12.4%)	4 (9.3%)	2 (6.7%)	6 (8.2%)
Unadjusted Relative Risk (95% CI)	1.97 (0.58, 6.73)					
p-value [1]	0.28					
Unadjusted Odds Ratio (95% CI)	2.14 (0.55, 8.32)					
p-value [1]	0.27					
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.05, 0.19)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1001: TEAEs of Grade 2 or less by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Skin and subcutaneous tissue disorders						
Night sweats	5 (7.6%)	2 (5.1%)	7 (6.7%)	2 (4.7%)	3 (10.0%)	5 (6.8%)
Unadjusted Relative Risk (95% CI)	1.48 (0.30, 7.25)					
p-value [1]	0.63					
Unadjusted Odds Ratio (95% CI)	1.52 (0.28, 8.22)					
p-value [1]	0.63					
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.07, 0.12)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Skin and subcutaneous tissue disorders						
Hyperhidrosis	2 (3.0%)	4 (10.3%)	6 (5.7%)	1 (2.3%)	2 (6.7%)	3 (4.1%)
Unadjusted Relative Risk (95% CI)	0.30 (0.06, 1.54)					
p-value [1]	0.15					
Unadjusted Odds Ratio (95% CI)	0.27 (0.05, 1.57)					
p-value [1]	0.15					
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.18, 0.03)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1001: TEAEs of Grade 2 or less by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC PT	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
Musculoskeletal and connective tissue disorders						
Any Event	21 (31.8%)	14 (35.9%)	35 (33.3%)	18 (41.9%)	11 (36.7%)	29 (39.7%)
Unadjusted Relative Risk (95% CI)	0.89 (0.51, 1.53)					
p-value [1]	0.67					
Unadjusted Odds Ratio (95% CI)	0.83 (0.36, 1.92)					
p-value [1]	0.67					
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.23, 0.15)					
Adjusted Relative Risk (95% CI) [2]	0.96 (0.55, 1.68)					
p-value [2]	0.89					
Musculoskeletal and connective tissue disorders						
Arthralgia	8 (12.1%)	3 (7.7%)	11 (10.5%)	3 (7.0%)	0	3 (4.1%)
Unadjusted Relative Risk (95% CI)	1.58 (0.44, 5.59)					
p-value [1]	0.48					
Unadjusted Odds Ratio (95% CI)	1.66 (0.41, 6.65)					
p-value [1]	0.48					
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.07, 0.16)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1001: TEAEs of Grade 2 or less by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Musculoskeletal and connective tissue disorders						
Pain in extremity	3 (4.5%)	4 (10.3%)	7 (6.7%)	6 (14.0%)	1 (3.3%)	7 (9.6%)
Unadjusted Relative Risk (95% CI)	0.44 (0.10, 1.88)					
p-value [1]	0.27					
Unadjusted Odds Ratio (95% CI)	0.42 (0.09, 1.97)					
p-value [1]	0.27					
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.16, 0.05)					
Adjusted Relative Risk (95% CI) [2]	0.51 (0.10, 2.52)					
p-value [2]	0.41					
Musculoskeletal and connective tissue disorders						
Back pain	2 (3.0%)	2 (5.1%)	4 (3.8%)	5 (11.6%)	1 (3.3%)	6 (8.2%)
Unadjusted Relative Risk (95% CI)	0.59 (0.09, 4.03)					
p-value [1]	0.59					
Unadjusted Odds Ratio (95% CI)	0.58 (0.08, 4.28)					
p-value [1]	0.59					
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.10, 0.06)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1001: TEAEs of Grade 2 or less by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC PT	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
Musculoskeletal and connective tissue disorders						
Bone pain	2 (3.0%)	4 (10.3%)	6 (5.7%)	1 (2.3%)	3 (10.0%)	4 (5.5%)
Unadjusted Relative Risk (95% CI)	0.30 (0.06, 1.54)					
p-value [1]	0.15					
Unadjusted Odds Ratio (95% CI)	0.27 (0.05, 1.57)					
p-value [1]	0.15					
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.18, 0.03)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Respiratory, thoracic and mediastinal disorders						
Any Event	21 (31.8%)	13 (33.3%)	34 (32.4%)	22 (51.2%)	11 (36.7%)	33 (45.2%)
Unadjusted Relative Risk (95% CI)	0.95 (0.54, 1.68)					
p-value [1]	0.87					
Unadjusted Odds Ratio (95% CI)	0.93 (0.40, 2.17)					
p-value [1]	0.87					
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.20, 0.17)					
Adjusted Relative Risk (95% CI) [2]	0.96 (0.55, 1.69)					
p-value [2]	0.90					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1001: TEAEs of Grade 2 or less by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Respiratory, thoracic and mediastinal disorders						
Cough	9 (13.6%)	4 (10.3%)	13 (12.4%)	13 (30.2%)	6 (20.0%)	19 (26.0%)
Unadjusted Relative Risk (95% CI)	1.33 (0.44, 4.03)					
p-value [1]	0.61					
Unadjusted Odds Ratio (95% CI)	1.38 (0.40, 4.83)					
p-value [1]	0.61					
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.09, 0.16)					
Adjusted Relative Risk (95% CI) [2]	1.32 (0.47, 3.73)					
p-value [2]	0.60					
Respiratory, thoracic and mediastinal disorders						
Dyspnoea	7 (10.6%)	6 (15.4%)	13 (12.4%)	4 (9.3%)	6 (20.0%)	10 (13.7%)
Unadjusted Relative Risk (95% CI)	0.69 (0.25, 1.90)					
p-value [1]	0.47					
Unadjusted Odds Ratio (95% CI)	0.65 (0.20, 2.10)					
p-value [1]	0.47					
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.18, 0.09)					
Adjusted Relative Risk (95% CI) [2]	0.77 (0.29, 2.02)					
p-value [2]	0.59					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1001: TEAEs of Grade 2 or less by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Respiratory, thoracic and mediastinal disorders						
Epistaxis	6 (9.1%)	5 (12.8%)	11 (10.5%)	1 (2.3%)	2 (6.7%)	3 (4.1%)
Unadjusted Relative Risk (95% CI)	0.71 (0.23, 2.17)					
p-value [1]	0.55					
Unadjusted Odds Ratio (95% CI)	0.68 (0.19, 2.40)					
p-value [1]	0.55					
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.16, 0.09)					
Adjusted Relative Risk (95% CI) [2]	0.71 (0.22, 2.28)					
p-value [2]	0.56					
Investigations						
Any Event	17 (25.8%)	3 (7.7%)	20 (19.0%)	17 (39.5%)	7 (23.3%)	24 (32.9%)
Unadjusted Relative Risk (95% CI)	3.35 (1.05, 10.70)					
p-value [1]	0.041					
Unadjusted Odds Ratio (95% CI)	4.16 (1.13, 15.29)					
p-value [1]	0.032					
Unadjusted Absolute Risk Difference (95% CI)	0.18 (0.05, 0.32)					
Adjusted Relative Risk (95% CI) [2]	3.14 (0.95, 10.34)					
p-value [2]	0.060					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1001: TEAEs of Grade 2 or less by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Investigations						
Weight decreased	7 (10.6%)	1 (2.6%)	8 (7.6%)	4 (9.3%)	4 (13.3%)	8 (11.0%)
Unadjusted Relative Risk (95% CI)	4.14 (0.53, 32.38)					
p-value [1]	0.18					
Unadjusted Odds Ratio (95% CI)	4.51 (0.53, 38.11)					
p-value [1]	0.17					
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.01, 0.17)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Blood and lymphatic system disorders						
Any Event	16 (24.2%)	6 (15.4%)	22 (21.0%)	8 (18.6%)	9 (30.0%)	17 (23.3%)
Unadjusted Relative Risk (95% CI)	1.58 (0.67, 3.69)					
p-value [1]	0.29					
Unadjusted Odds Ratio (95% CI)	1.76 (0.62, 4.96)					
p-value [1]	0.28					
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.06, 0.24)					
Adjusted Relative Risk (95% CI) [2]	1.55 (0.66, 3.63)					
p-value [2]	0.31					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1001: TEAEs of Grade 2 or less by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC PT	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
Blood and lymphatic system disorders						
Thrombocytopenia	6 (9.1%)	2 (5.1%)	8 (7.6%)	3 (7.0%)	5 (16.7%)	8 (11.0%)
Unadjusted Relative Risk (95% CI)	1.77 (0.38, 8.36)					
p-value [1]	0.47					
Unadjusted Odds Ratio (95% CI)	1.85 (0.35, 9.65)					
p-value [1]	0.47					
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.06, 0.14)					
Adjusted Relative Risk (95% CI) [2]	1.92 (0.40, 9.28)					
p-value [2]	0.42					
Psychiatric disorders						
Any Event	8 (12.1%)	5 (12.8%)	13 (12.4%)	10 (23.3%)	7 (23.3%)	17 (23.3%)
Unadjusted Relative Risk (95% CI)	0.95 (0.33, 2.69)					
p-value [1]	0.92					
Unadjusted Odds Ratio (95% CI)	0.94 (0.28, 3.10)					
p-value [1]	0.92					
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.14, 0.12)					
Adjusted Relative Risk (95% CI) [2]	1.01 (0.36, 2.87)					
p-value [2]	0.99					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1001: TEAEs of Grade 2 or less by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Psychiatric disorders						
Insomnia	2 (3.0%)	3 (7.7%)	5 (4.8%)	4 (9.3%)	3 (10.0%)	7 (9.6%)
Unadjusted Relative Risk (95% CI)	0.39 (0.07, 2.26)					
p-value [1]	0.30					
Unadjusted Odds Ratio (95% CI)	0.38 (0.06, 2.35)					
p-value [1]	0.29					
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.14, 0.05)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Eye disorders						
Any Event	7 (10.6%)	4 (10.3%)	11 (10.5%)	4 (9.3%)	4 (13.3%)	8 (11.0%)
Unadjusted Relative Risk (95% CI)	1.03 (0.32, 3.31)					
p-value [1]	0.95					
Unadjusted Odds Ratio (95% CI)	1.04 (0.28, 3.80)					
p-value [1]	0.95					
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.12, 0.12)					
Adjusted Relative Risk (95% CI) [2]	1.04 (0.34, 3.16)					
p-value [2]	0.94					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1001: TEAEs of Grade 2 or less by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Vascular disorders						
Any Event	7 (10.6%)	1 (2.6%)	8 (7.6%)	8 (18.6%)	6 (20.0%)	14 (19.2%)
Unadjusted Relative Risk (95% CI)	4.14 (0.53, 32.38)					
p-value [1]	0.18					
Unadjusted Odds Ratio (95% CI)	4.51 (0.53, 38.11)					
p-value [1]	0.17					
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.01, 0.17)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Injury, poisoning and procedural complications						
Any Event	6 (9.1%)	4 (10.3%)	10 (9.5%)	4 (9.3%)	3 (10.0%)	7 (9.6%)
Unadjusted Relative Risk (95% CI)	0.89 (0.27, 2.95)					
p-value [1]	0.84					
Unadjusted Odds Ratio (95% CI)	0.88 (0.23, 3.32)					
p-value [1]	0.84					
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.13, 0.11)					
Adjusted Relative Risk (95% CI) [2]	0.88 (0.30, 2.62)					
p-value [2]	0.82					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1001: TEAEs of Grade 2 or less by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Renal and urinary disorders						
Any Event	5 (7.6%)	2 (5.1%)	7 (6.7%)	12 (27.9%)	9 (30.0%)	21 (28.8%)
Unadjusted Relative Risk (95% CI)	1.48 (0.30, 7.25)					
p-value [1]	0.63					
Unadjusted Odds Ratio (95% CI)	1.52 (0.28, 8.22)					
p-value [1]	0.63					
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.07, 0.12)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Renal and urinary disorders						
Acute kidney injury	1 (1.5%)	0	1 (1.0%)	4 (9.3%)	3 (10.0%)	7 (9.6%)
Unadjusted Relative Risk (95% CI)	1.79 (0.07, 42.92)					
p-value [1]	0.72					
Unadjusted Odds Ratio (95% CI)	1.81 (0.07, 45.50)					
p-value [1]	0.72					
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.04, 0.06)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.1001: TEAEs of Grade 2 or less by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Cardiac disorders						
Any Event	3 (4.5%)	3 (7.7%)	6 (5.7%)	7 (16.3%)	5 (16.7%)	12 (16.4%)
Unadjusted Relative Risk (95% CI)	0.59 (0.13, 2.79)					
p-value [1]	0.51					
Unadjusted Odds Ratio (95% CI)	0.57 (0.11, 2.98)					
p-value [1]	0.51					
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.13, 0.07)					
Adjusted Relative Risk (95% CI) [2]	0.63 (0.16, 2.54)					
p-value [2]	0.52					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

2.10.4 SUE

GSK Oncology
Study GS-US-352-1214

Table 3.3501: Serious TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Any Serious TEAE						
Number of Subjects With Any Event	23 (34.8%)	9 (23.1%)	32 (30.5%)	26 (60.5%)	13 (43.3%)	39 (53.4%)
Unadjusted Relative Risk (95% CI)	1.51 (0.78, 2.93)					
p-value [1]	0.22					
Unadjusted Odds Ratio (95% CI)	1.78 (0.72, 4.39)					
p-value [1]	0.21					
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.06, 0.29)					
Adjusted Relative Risk (95% CI) [2]	1.44 (0.74, 2.80)					
p-value [2]	0.28					
Infections and infestations						
Any Event	8 (12.1%)	5 (12.8%)	13 (12.4%)	13 (30.2%)	4 (13.3%)	17 (23.3%)
Unadjusted Relative Risk (95% CI)	0.95 (0.33, 2.69)					
p-value [1]	0.92					
Unadjusted Odds Ratio (95% CI)	0.94 (0.28, 3.10)					
p-value [1]	0.92					
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.14, 0.12)					
Adjusted Relative Risk (95% CI) [2]	0.93 (0.31, 2.75)					
p-value [2]	0.89					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.3501: Serious TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Infections and infestations						
Pneumonia	2 (3.0%)	1 (2.6%)	3 (2.9%)	6 (14.0%)	1 (3.3%)	7 (9.6%)
Unadjusted Relative Risk (95% CI)	1.18 (0.11, 12.61)					
p-value [1]	0.89					
Unadjusted Odds Ratio (95% CI)	1.19 (0.10, 13.54)					
p-value [1]	0.89					
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.06, 0.07)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Infections and infestations						
Sepsis	2 (3.0%)	2 (5.1%)	4 (3.8%)	4 (9.3%)	1 (3.3%)	5 (6.8%)
Unadjusted Relative Risk (95% CI)	0.59 (0.09, 4.03)					
p-value [1]	0.59					
Unadjusted Odds Ratio (95% CI)	0.58 (0.08, 4.28)					
p-value [1]	0.59					
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.10, 0.06)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.3501: Serious TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Cardiac disorders						
Any Event	5 (7.6%)	1 (2.6%)	6 (5.7%)	4 (9.3%)	2 (6.7%)	6 (8.2%)
Unadjusted Relative Risk (95% CI)	2.95 (0.36, 24.38)					
p-value [1]	0.31					
Unadjusted Odds Ratio (95% CI)	3.11 (0.35, 27.69)					
p-value [1]	0.31					
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.03, 0.13)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Gastrointestinal disorders						
Any Event	5 (7.6%)	2 (5.1%)	7 (6.7%)	2 (4.7%)	3 (10.0%)	5 (6.8%)
Unadjusted Relative Risk (95% CI)	1.48 (0.30, 7.25)					
p-value [1]	0.63					
Unadjusted Odds Ratio (95% CI)	1.52 (0.28, 8.22)					
p-value [1]	0.63					
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.07, 0.12)					
Adjusted Relative Risk (95% CI) [2]	1.43 (0.33, 6.30)					
p-value [2]	0.63					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.3501: Serious TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Gastrointestinal disorders						
Abdominal pain	0	2 (5.1%)	2 (1.9%)	0	0	0
Unadjusted Relative Risk (95% CI)	0.12 (0.01, 2.42)					
p-value [1]	0.17					
Unadjusted Odds Ratio (95% CI)	0.11 (0.01, 2.41)					
p-value [1]	0.16					
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.13, 0.02)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Respiratory, thoracic and mediastinal disorders						
Any Event	4 (6.1%)	1 (2.6%)	5 (4.8%)	7 (16.3%)	3 (10.0%)	10 (13.7%)
Unadjusted Relative Risk (95% CI)	2.36 (0.27, 20.40)					
p-value [1]	0.43					
Unadjusted Odds Ratio (95% CI)	2.45 (0.26, 22.76)					
p-value [1]	0.43					
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.04, 0.11)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.3501: Serious TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
General disorders and administration site conditions						
Any Event	3 (4.5%)	0	3 (2.9%)	2 (4.7%)	3 (10.0%)	5 (6.8%)
Unadjusted Relative Risk (95% CI)	4.18 (0.22, 78.83)					
p-value [1]	0.34					
Unadjusted Odds Ratio (95% CI)	4.35 (0.22, 86.57)					
p-value [1]	0.33					
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.02, 0.10)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
General disorders and administration site conditions						
Pyrexia	2 (3.0%)	0	2 (1.9%)	2 (4.7%)	3 (10.0%)	5 (6.8%)
Unadjusted Relative Risk (95% CI)	2.99 (0.15, 60.62)					
p-value [1]	0.48					
Unadjusted Odds Ratio (95% CI)	3.06 (0.14, 65.44)					
p-value [1]	0.47					
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.03, 0.08)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.3501: Serious TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Nervous system disorders						
Any Event	3 (4.5%)	0	3 (2.9%)	4 (9.3%)	0	4 (5.5%)
Unadjusted Relative Risk (95% CI)	4.18 (0.22, 78.83)					
p-value [1]	0.34					
Unadjusted Odds Ratio (95% CI)	4.35 (0.22, 86.57)					
p-value [1]	0.33					
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.02, 0.10)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Renal and urinary disorders						
Any Event	3 (4.5%)	0	3 (2.9%)	6 (14.0%)	1 (3.3%)	7 (9.6%)
Unadjusted Relative Risk (95% CI)	4.18 (0.22, 78.83)					
p-value [1]	0.34					
Unadjusted Odds Ratio (95% CI)	4.35 (0.22, 86.57)					
p-value [1]	0.33					
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.02, 0.10)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.3501: Serious TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Blood and lymphatic system disorders						
Any Event	2 (3.0%)	1 (2.6%)	3 (2.9%)	1 (2.3%)	4 (13.3%)	5 (6.8%)
Unadjusted Relative Risk (95% CI)	1.18 (0.11, 12.61)					
p-value [1]	0.89					
Unadjusted Odds Ratio (95% CI)	1.19 (0.10, 13.54)					
p-value [1]	0.89					
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.06, 0.07)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Blood and lymphatic system disorders						
Anaemia	2 (3.0%)	0	2 (1.9%)	1 (2.3%)	3 (10.0%)	4 (5.5%)
Unadjusted Relative Risk (95% CI)	2.99 (0.15, 60.62)					
p-value [1]	0.48					
Unadjusted Odds Ratio (95% CI)	3.06 (0.14, 65.44)					
p-value [1]	0.47					
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.03, 0.08)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.3501: Serious TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Blood and lymphatic system disorders						
Splenic infarction	0	0	0	0	3 (10.0%)	3 (4.1%)
Unadjusted Relative Risk (95% CI)	NE					
p-value [1]	NE					
Unadjusted Odds Ratio (95% CI)	NE					
p-value [1]	NE					
Unadjusted Absolute Risk Difference (95% CI)	NE					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Injury, poisoning and procedural complications						
Any Event	1 (1.5%)	0	1 (1.0%)	3 (7.0%)	0	3 (4.1%)
Unadjusted Relative Risk (95% CI)	1.79 (0.07, 42.92)					
p-value [1]	0.72					
Unadjusted Odds Ratio (95% CI)	1.81 (0.07, 45.50)					
p-value [1]	0.72					
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.04, 0.06)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.3501: Serious TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Metabolism and nutrition disorders						
Any Event	1 (1.5%)	1 (2.6%)	2 (1.9%)	1 (2.3%)	2 (6.7%)	3 (4.1%)
Unadjusted Relative Risk (95% CI)	0.59 (0.04, 9.18)					
p-value [1]	0.71					
Unadjusted Odds Ratio (95% CI)	0.58 (0.04, 9.62)					
p-value [1]	0.71					
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.07, 0.05)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Metabolism and nutrition disorders						
Hyponatraemia	0	0	0	0	2 (6.7%)	2 (2.7%)
Unadjusted Relative Risk (95% CI)	NE					
p-value [1]	NE					
Unadjusted Odds Ratio (95% CI)	NE					
p-value [1]	NE					
Unadjusted Absolute Risk Difference (95% CI)	NE					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.3501: Serious TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Musculoskeletal and connective tissue disorders						
Any Event	1 (1.5%)	0	1 (1.0%)	0	2 (6.7%)	2 (2.7%)
Unadjusted Relative Risk (95% CI)	1.79 (0.07, 42.92)					
p-value [1]	0.72					
Unadjusted Odds Ratio (95% CI)	1.81 (0.07, 45.50)					
p-value [1]	0.72					
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.04, 0.06)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Vascular disorders						
Any Event	1 (1.5%)	1 (2.6%)	2 (1.9%)	4 (9.3%)	0	4 (5.5%)
Unadjusted Relative Risk (95% CI)	0.59 (0.04, 9.18)					
p-value [1]	0.71					
Unadjusted Odds Ratio (95% CI)	0.58 (0.04, 9.62)					
p-value [1]	0.71					
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.07, 0.05)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.3501: Serious TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Hepatobiliary disorders						
Any Event	0	0	0	3 (7.0%)	0	3 (4.1%)
Unadjusted Relative Risk (95% CI)	NE					
p-value [1]	NE					
Unadjusted Odds Ratio (95% CI)	NE					
p-value [1]	NE					
Unadjusted Absolute Risk Difference (95% CI)	NE					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					
Psychiatric disorders						
Any Event	0	0	0	0	2 (6.7%)	2 (2.7%)
Unadjusted Relative Risk (95% CI)	NE					
p-value [1]	NE					
Unadjusted Odds Ratio (95% CI)	NE					
p-value [1]	NE					
Unadjusted Absolute Risk Difference (95% CI)	NE					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

Table 3.3501: Serious TEAEs by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
SOC	MMB	BAT	Total	(MMB->MMB)	(BAT->MMB)	Total
PT	(N=66)	(N=39)	(N=105)	(N=43)	(N=30)	(N=73)
Psychiatric disorders						
Confusional state	0	0	0	0	2 (6.7%)	2 (2.7%)
Unadjusted Relative Risk (95% CI)	NE					
p-value [1]	NE					
Unadjusted Odds Ratio (95% CI)	NE					
p-value [1]	NE					
Unadjusted Absolute Risk Difference (95% CI)	NE					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
Data Extracted: CRF data: 25JUN2019

2.10.5 Therapieabbrüche

GSK Oncology
Study GS-US-352-1214

Table 3.1301: Any TEAE leading to discontinuation of Study Drug by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase
SAF-Anemic Analysis Set

	Randomized Treatment Phase			Extended Treatment Phase		
	MMB (N=66)	BAT (N=39)	Total (N=105)	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)
Subjects with Any TEAE	14 (21.2%)	1 (2.6%)	15 (14.3%)	13 (30.2%)	15 (50.0%)	28 (38.4%)
Number of Subjects, By SOC And PT						
Blood and lymphatic system disorders	4 (6.1%)	1 (2.6%)	5 (4.8%)	2 (4.7%)	4 (13.3%)	6 (8.2%)
Thrombocytopenia	3 (4.5%)	0	3 (2.9%)	1 (2.3%)	4 (13.3%)	5 (6.8%)
Splenomegaly	1 (1.5%)	0	1 (1.0%)	0	0	0
Haemolytic anaemia	0	1 (2.6%)	1 (1.0%)	0	0	0
Neutropenia	0	0	0	1 (2.3%)	0	1 (1.4%)
Gastrointestinal disorders	2 (3.0%)	0	2 (1.9%)	0	4 (13.3%)	4 (5.5%)
Abdominal pain	1 (1.5%)	0	1 (1.0%)	0	0	0
Abdominal pain upper	1 (1.5%)	0	1 (1.0%)	0	0	0
Diarrhoea	0	0	0	0	3 (10.0%)	3 (4.1%)
Dysphagia	0	0	0	0	1 (3.3%)	1 (1.4%)
Vomiting	0	0	0	0	1 (3.3%)	1 (1.4%)
Infections and infestations	2 (3.0%)	0	2 (1.9%)	2 (4.7%)	2 (6.7%)	4 (5.5%)
Pneumonia	1 (1.5%)	0	1 (1.0%)	0	1 (3.3%)	1 (1.4%)
Sepsis	1 (1.5%)	0	1 (1.0%)	0	1 (3.3%)	1 (1.4%)
Upper respiratory tract infection	1 (1.5%)	0	1 (1.0%)	0	0	0
Bacteraemia	0	0	0	1 (2.3%)	0	1 (1.4%)
Clostridium difficile infection	0	0	0	1 (2.3%)	0	1 (1.4%)
Investigations	2 (3.0%)	0	2 (1.9%)	0	2 (6.7%)	2 (2.7%)
Blood creatinine increased	1 (1.5%)	0	1 (1.0%)	0	0	0
Gamma-glutamyltransferase increased	1 (1.5%)	0	1 (1.0%)	0	0	0
Liver function test increased	0	0	0	0	1 (3.3%)	1 (1.4%)
Weight decreased	0	0	0	0	1 (3.3%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
SOCs and PTs (within each SOC) were presented by descending order of frequency under 'MMB' column
Multiple AEs were counted only once per subject for each SOC and PT
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-teae-disc.sas V.03.05 Output file: t-teae-disc.pdf 24AUG2023:16:53

Table 3.1301: Any TEAE leading to discontinuation of Study Drug by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase
SAF-Anemic Analysis Set

	Randomized Treatment Phase			Extended Treatment Phase		
	MMB (N=66)	BAT (N=39)	Total (N=105)	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (3.0%)	0	2 (1.9%)	1 (2.3%)	0	1 (1.4%)
Acute myeloid leukaemia	1 (1.5%)	0	1 (1.0%)	1 (2.3%)	0	1 (1.4%)
Leukaemia	1 (1.5%)	0	1 (1.0%)	0	0	0
Cardiac disorders	1 (1.5%)	0	1 (1.0%)	2 (4.7%)	0	2 (2.7%)
Atrial fibrillation	1 (1.5%)	0	1 (1.0%)	0	0	0
Cardiac failure	1 (1.5%)	0	1 (1.0%)	1 (2.3%)	0	1 (1.4%)
Cardiac failure acute	0	0	0	1 (2.3%)	0	1 (1.4%)
General disorders and administration site conditions	1 (1.5%)	0	1 (1.0%)	3 (7.0%)	1 (3.3%)	4 (5.5%)
Disease progression	1 (1.5%)	0	1 (1.0%)	1 (2.3%)	0	1 (1.4%)
Asthenia	0	0	0	0	1 (3.3%)	1 (1.4%)
Oedema peripheral	0	0	0	1 (2.3%)	0	1 (1.4%)
Pyrexia	0	0	0	1 (2.3%)	0	1 (1.4%)
Nervous system disorders	1 (1.5%)	0	1 (1.0%)	3 (7.0%)	4 (13.3%)	7 (9.6%)
Peripheral sensory neuropathy	1 (1.5%)	0	1 (1.0%)	0	2 (6.7%)	2 (2.7%)
Cerebrovascular accident	0	0	0	1 (2.3%)	0	1 (1.4%)
Headache	0	0	0	0	2 (6.7%)	2 (2.7%)
Peripheral sensorimotor neuropathy	0	0	0	1 (2.3%)	0	1 (1.4%)
Subarachnoid haemorrhage	0	0	0	1 (2.3%)	0	1 (1.4%)
Renal and urinary disorders	1 (1.5%)	0	1 (1.0%)	3 (7.0%)	0	3 (4.1%)
Renal failure	1 (1.5%)	0	1 (1.0%)	2 (4.7%)	0	2 (2.7%)
Renal impairment	0	0	0	1 (2.3%)	0	1 (1.4%)
Respiratory, thoracic and mediastinal disorders	0	0	0	1 (2.3%)	0	1 (1.4%)
Pneumonia aspiration	0	0	0	1 (2.3%)	0	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
SOCs and PTs (within each SOC) were presented by descending order of frequency under 'MMB' column
Multiple AEs were counted only once per subject for each SOC and PT
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 25JUN2019

Table 3.1301: Any TEAE leading to discontinuation of Study Drug by SOC and PT
Randomized Treatment Phase and Extended Treatment Phase
SAF-Anemic Analysis Set

	Randomized Treatment Phase			Extended Treatment Phase		
	MMB (N=66)	BAT (N=39)	Total (N=105)	Continuing (MMB->MMB) (N=43)	Switch (BAT->MMB) (N=30)	Total (N=73)
Skin and subcutaneous tissue disorders	0	0	0	1 (2.3%)	0	1 (1.4%)
Skin ulcer	0	0	0	1 (2.3%)	0	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
SOCs and PTs (within each SOC) were presented by descending order of frequency under 'MMB' column
Multiple AEs were counted only once per subject for each SOC and PT
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term

Data Extracted: CRF data: 25JUN2019

2.10.6 UESI

GSK Oncology
Study GS-US-352-1214

Table 3.3801: Any TE AESI
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
Number of subjects, n(%)	65 (98.5%)	34 (87.2%)	99 (94.3%)	42 (97.7%)	30 (100.0%)	72 (98.6%)
Unadjusted Relative Risk (95% CI)	1.13 (1.00, 1.28)					
p-value [1]	0.054					
Unadjusted Odds Ratio (95% CI)	9.56 (1.07, 85.14)					
p-value [1]	0.043					
Unadjusted Absolute Risk Difference (95% CI)	0.11 (0.00, 0.22)					
Adjusted Relative Risk (95% CI) [2]	1.12 (0.99, 1.28)					
p-value [2]	0.082					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
TE AESI = Treatment-Emergent Adverse Event of Special Interest
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-aesi-gba.sas V.03.05 Output file: t-aesum-aesi-gba.pdf 24AUG2023:17:00

Table 3.4001: Any TE AESI of Grade 3 or more
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
Number of subjects, n(%)	30 (45.5%)	14 (35.9%)	44 (41.9%)	27 (62.8%)	19 (63.3%)	46 (63.0%)
Unadjusted Relative Risk (95% CI)	1.27 (0.77, 2.08)					
p-value [1]	0.35					
Unadjusted Odds Ratio (95% CI)	1.49 (0.66, 3.36)					
p-value [1]	0.34					
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.10, 0.29)					
Adjusted Relative Risk (95% CI) [2]	1.31 (0.80, 2.13)					
p-value [2]	0.29					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Severity grades were defined by CTCAE Version 4.03
TE AESI = Treatment-Emergent Adverse Event of Special Interest
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-aesi-gba.sas V.03.05 Output file: t-aesum-aesi-gge3-gba.pdf 24AUG2023:17:00

Table 3.3901: Any TE AESI of Grade 2 or less
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
Number of subjects, n(%)	64 (97.0%)	34 (87.2%)	98 (93.3%)	42 (97.7%)	29 (96.7%)	71 (97.3%)
Unadjusted Relative Risk (95% CI)	1.11 (0.98, 1.26)					
p-value [1]	0.10					
Unadjusted Odds Ratio (95% CI)	4.71 (0.87, 25.55)					
p-value [1]	0.073					
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.01, 0.21)					
Adjusted Relative Risk (95% CI) [2]	1.11 (0.97, 1.26)					
p-value [2]	0.13					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Severity grades were defined by CTCAE Version 4.03
TE AESI = Treatment-Emergent Adverse Event of Special Interest
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.4101: Any Serious TE AESI
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
Number of subjects, n(%)	21 (31.8%)	9 (23.1%)	30 (28.6%)	25 (58.1%)	12 (40.0%)	37 (50.7%)
Unadjusted Relative Risk (95% CI)	1.38 (0.70, 2.70)					
p-value [1]	0.35					
Unadjusted Odds Ratio (95% CI)	1.56 (0.63, 3.85)					
p-value [1]	0.34					
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.09, 0.26)					
Adjusted Relative Risk (95% CI) [2]	1.32 (0.67, 2.60)					
p-value [2]	0.42					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
TE AESI = Treatment-Emergent Adverse Event of Special Interest
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2601: TEAEs of Cataract MST
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
Number of subjects, n(%)	3 (4.5%)	0	3 (2.9%)	1 (2.3%)	0	1 (1.4%)
Unadjusted Relative Risk (95% CI)	4.18 (0.22, 78.83)					
p-value [1]	0.34					
Unadjusted Odds Ratio (95% CI)	4.35 (0.22, 86.57)					
p-value [1]	0.33					
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.02, 0.10)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
TEAE = Treatment-Emergent Adverse Event
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge so these values are presented as NE.

Data Extracted: CRF data: 25JUN2019

Table 3.2801: TEAEs of Cataract MST of Grade 3 or more
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Severity grades were defined by CTCAE Version 4.03
TEAE = Treatment-Emergent Adverse Event

Data Extracted: CRF data: 25JUN2019

Table 3.2701: TEAEs of Cataract MST of Grade 2 or less
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
Number of subjects, n(%)	3 (4.5%)	0	3 (2.9%)	1 (2.3%)	0	1 (1.4%)
Unadjusted Relative Risk (95% CI)	4.18 (0.22, 78.83)					
p-value [1]	0.34					
Unadjusted Odds Ratio (95% CI)	4.35 (0.22, 86.57)					
p-value [1]	0.33					
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.02, 0.10)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Severity grades were defined by CTCAE Version 4.03
TEAE = Treatment-Emergent Adverse Event
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge so these values are presented as NE.

Data Extracted: CRF data: 25JUN2019

Table 3.2901: Serious TEAEs of Cataract MST
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
TEAE = Treatment-Emergent Adverse Event

Data Extracted: CRF data: 25JUN2019

Table 3.3001: TEAEs of First Dose Effect
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
Number of subjects, n(%)	1 (1.5%)	0	1 (1.0%)	-	2 (6.7%)	-
Unadjusted Relative Risk (95% CI)	1.79 (0.07, 42.92)					
p-value [1]	0.72					
Unadjusted Odds Ratio (95% CI)	1.81 (0.07, 45.50)					
p-value [1]	0.72					
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.04, 0.06)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
TEAE = Treatment-Emergent Adverse Event
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge so these values are presented as NE.

Data Extracted: CRF data: 25JUN2019

Table 3.3201: TEAEs of First Dose Effect of Grade 3 or more
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Severity grades were defined by CTCAE Version 4.03
TEAE = Treatment-Emergent Adverse Event

Data Extracted: CRF data: 25JUN2019

Table 3.3101: TEAEs of First Dose Effect of Grade 2 or less
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
Number of subjects, n(%)	1 (1.5%)	0	1 (1.0%)	-	2 (6.7%)	-
Unadjusted Relative Risk (95% CI)	1.79 (0.07, 42.92)					
p-value [1]	0.72					
Unadjusted Odds Ratio (95% CI)	1.81 (0.07, 45.50)					
p-value [1]	0.72					
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.04, 0.06)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Severity grades were defined by CTCAE Version 4.03
TEAE = Treatment-Emergent Adverse Event
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge so these values are presented as NE.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-fds-gba.sas V.03.05 Output file: t-aesum-fds-gle2-gba.pdf 24AUG2023:16:57

Table 3.3301: Serious TEAEs of First Dose Effect
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
TEAE = Treatment-Emergent Adverse Event

Data Extracted: CRF data: 25JUN2019

Table 3.2201: TEAEs of Non-Hematological MST
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
Number of subjects, n(%)	65 (98.5%)	34 (87.2%)	99 (94.3%)	42 (97.7%)	30 (100.0%)	72 (98.6%)
Unadjusted Relative Risk (95% CI)	1.13 (1.00, 1.28)					
p-value [1]	0.054					
Unadjusted Odds Ratio (95% CI)	9.56 (1.07, 85.14)					
p-value [1]	0.043					
Unadjusted Absolute Risk Difference (95% CI)	0.11 (0.00, 0.22)					
Adjusted Relative Risk (95% CI) [2]	1.12 (0.99, 1.28)					
p-value [2]	0.082					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
TEAE = Treatment-Emergent Adverse Event
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-nh-gba.sas V.03.05 Output file: t-aesum-nh-gba.pdf 24AUG2023:16:52

Table 3.2401: TEAEs of Non-Hematological MST of Grade 3 or more
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
Number of subjects, n(%)	30 (45.5%)	14 (35.9%)	44 (41.9%)	27 (62.8%)	19 (63.3%)	46 (63.0%)
Unadjusted Relative Risk (95% CI)	1.27 (0.77, 2.08)					
p-value [1]	0.35					
Unadjusted Odds Ratio (95% CI)	1.49 (0.66, 3.36)					
p-value [1]	0.34					
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.10, 0.29)					
Adjusted Relative Risk (95% CI) [2]	1.31 (0.80, 2.13)					
p-value [2]	0.29					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Severity grades were defined by CTCAE Version 4.03
TEAE = Treatment-Emergent Adverse Event
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-nh-gba.sas V.03.05 Output file: t-aesum-nh-gge3-gba.pdf 24AUG2023:16:53

Table 3.2301: TEAEs of Non-Hematological MST of Grade 2 or less
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing Switch		
	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
Number of subjects, n(%)	64 (97.0%)	34 (87.2%)	98 (93.3%)	42 (97.7%)	29 (96.7%)	71 (97.3%)
Unadjusted Relative Risk (95% CI)	1.11 (0.98, 1.26)					
p-value [1]	0.10					
Unadjusted Odds Ratio (95% CI)	4.71 (0.87, 25.55)					
p-value [1]	0.073					
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.01, 0.21)					
Adjusted Relative Risk (95% CI) [2]	1.11 (0.97, 1.26)					
p-value [2]	0.13					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Severity grades were defined by CTCAE Version 4.03
TEAE = Treatment-Emergent Adverse Event
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-nh-gba.sas V.03.05 Output file: t-aesum-nh-gle2-gba.pdf 24AUG2023:16:53

Table 3.2501: Serious TEAEs of Non-Hematological MST
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
Number of subjects, n(%)	21 (31.8%)	9 (23.1%)	30 (28.6%)	25 (58.1%)	12 (40.0%)	37 (50.7%)
Unadjusted Relative Risk (95% CI)	1.38 (0.70, 2.70)					
p-value [1]	0.35					
Unadjusted Odds Ratio (95% CI)	1.56 (0.63, 3.85)					
p-value [1]	0.34					
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.09, 0.26)					
Adjusted Relative Risk (95% CI) [2]	1.32 (0.67, 2.60)					
p-value [2]	0.42					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
TEAE = Treatment-Emergent Adverse Event
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-nh-gba.sas V.03.05 Output file: t-aesum-nh-ser-gba.pdf 24AUG2023:16:53

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Table 3.1801: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug

Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)

SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)			
				Continuing	Switch		
	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)	
Number of subjects, n(%)	1 (1.5%)	0	1 (1.0%)	1 (2.3%)	2 (6.7%)	3 (4.1%)	
Unadjusted Relative Risk (95% CI)	1.79 (0.07, 42.92)						
p-value [1]	0.72						
Unadjusted Odds Ratio (95% CI)	1.81 (0.07, 45.50)						
p-value [1]	0.72						
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.04, 0.06)						
Adjusted Relative Risk (95% CI) [2]	NE						
p-value [2]	NE						

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.

Adverse events were mapped according to MedDRA Version 22.0

TEAE = Treatment-Emergent Adverse Event

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge so these values are presented as NE.

Data Extracted: CRF data: 25JUN2019

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Table 3.2001: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug of Grade 3 or more

Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)

SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
Number of subjects, n(%)	0	0	0	0	1 (3.3%)	1 (1.4%)
Unadjusted Relative Risk (95% CI)	NE					
p-value [1]	NE					
Unadjusted Odds Ratio (95% CI)	NE					
p-value [1]	NE					
Unadjusted Absolute Risk Difference (95% CI)	NE					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.

Adverse events were mapped according to MedDRA Version 22.0

Severity grades were defined by CTCAE Version 4.03

TEAE = Treatment-Emergent Adverse Event

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge so these values are presented as NE.

Data Extracted: CRF data: 25JUN2019

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Table 3.1901: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug of Grade 2 or less

Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)

SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
Number of subjects, n(%)	1 (1.5%)	0	1 (1.0%)	1 (2.3%)	1 (3.3%)	2 (2.7%)
Unadjusted Relative Risk (95% CI)	1.79 (0.07, 42.92)					
p-value [1]	0.72					
Unadjusted Odds Ratio (95% CI)	1.81 (0.07, 45.50)					
p-value [1]	0.72					
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.04, 0.06)					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.

Adverse events were mapped according to MedDRA Version 22.0

Severity grades were defined by CTCAE Version 4.03

TEAE = Treatment-Emergent Adverse Event

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge so these values are presented as NE.

Data Extracted: CRF data: 25JUN2019

Table 3.1401: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only)
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)			
				Continuing	Switch		
	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)	
Number of subjects, n(%)	7 (10.6%)	0	7 (6.7%)	5 (11.6%)	7 (23.3%)	12 (16.4%)	
Unadjusted Relative Risk (95% CI)	8.96 (0.53, 152.64)						
p-value [1]	0.13						
Unadjusted Odds Ratio (95% CI)	9.96 (0.55, 179.34)						
p-value [1]	0.12						
Unadjusted Absolute Risk Difference (95% CI)	0.10 (0.02, 0.18)						
Adjusted Relative Risk (95% CI) [2]	NE						
p-value [2]	NE						

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
TEAE = Treatment-Emergent Adverse Event
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge so these values are presented as NE.

Data Extracted: CRF data: 25JUN2019

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Table 3.1601: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 3 or more

Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)

SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)		
				Continuing	Switch	
	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	Total (N=73)
Number of subjects, n(%)	0	0	0	0	1 (3.3%)	1 (1.4%)
Unadjusted Relative Risk (95% CI)	NE					
p-value [1]	NE					
Unadjusted Odds Ratio (95% CI)	NE					
p-value [1]	NE					
Unadjusted Absolute Risk Difference (95% CI)	NE					
Adjusted Relative Risk (95% CI) [2]	NE					
p-value [2]	NE					

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.

Adverse events were mapped according to MedDRA Version 22.0

Severity grades were defined by CTCAE Version 4.03

TEAE = Treatment-Emergent Adverse Event

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge so these values are presented as NE.

Data Extracted: CRF data: 25JUN2019

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Table 3.1501: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 2 or less

Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)

SAF-Anemic Analysis Set

	Randomized Phase			ET Phase (Week 24 Onward)			
				Continuing	Switch		
	MMB (N=66)	BAT (N=39)	Total (N=105)	(MMB->MMB) (N=43)	(BAT->MMB) (N=30)	(N=73)	Total
Number of subjects, n(%)	7 (10.6%)	0	7 (6.7%)	5 (11.6%)	7 (23.3%)	12 (16.4%)	
Unadjusted Relative Risk (95% CI)	8.96 (0.53, 152.64)						
p-value [1]	0.13						
Unadjusted Odds Ratio (95% CI)	9.96 (0.55, 179.34)						
p-value [1]	0.12						
Unadjusted Absolute Risk Difference (95% CI)	0.10 (0.02, 0.18)						
Adjusted Relative Risk (95% CI) [2]	NE						
p-value [2]	NE						

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.

Adverse events were mapped according to MedDRA Version 22.0

Severity grades were defined by CTCAE Version 4.03

TEAE = Treatment-Emergent Adverse Event

[1] p-values were obtained from a Z-test.

[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge so these values are presented as NE.

Data Extracted: CRF data: 25JUN2019

Table 3.1701: Serious TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only)
Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
TEAE = Treatment-Emergent Adverse Event

Data Extracted: CRF data: 25JUN2019

GSK Oncology

Study GS-US-352-1214

Table 3.2101: Serious TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug

Randomized Treatment Phase and Extended Treatment Phase (Week 24 Onward)

SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.

Adverse events were mapped according to MedDRA Version 22.0

TEAE = Treatment-Emergent Adverse Event

Data Extracted: CRF data: 25JUN2019

3 MOMENTUM

3.1 Milzansprechen

GSK Oncology
Study SRA-MMB-301

Table 2.0601: Splenic Response Rate at Week 24 (25% reduction criterion)
Intent-To-Treat (ITT) Analysis Set

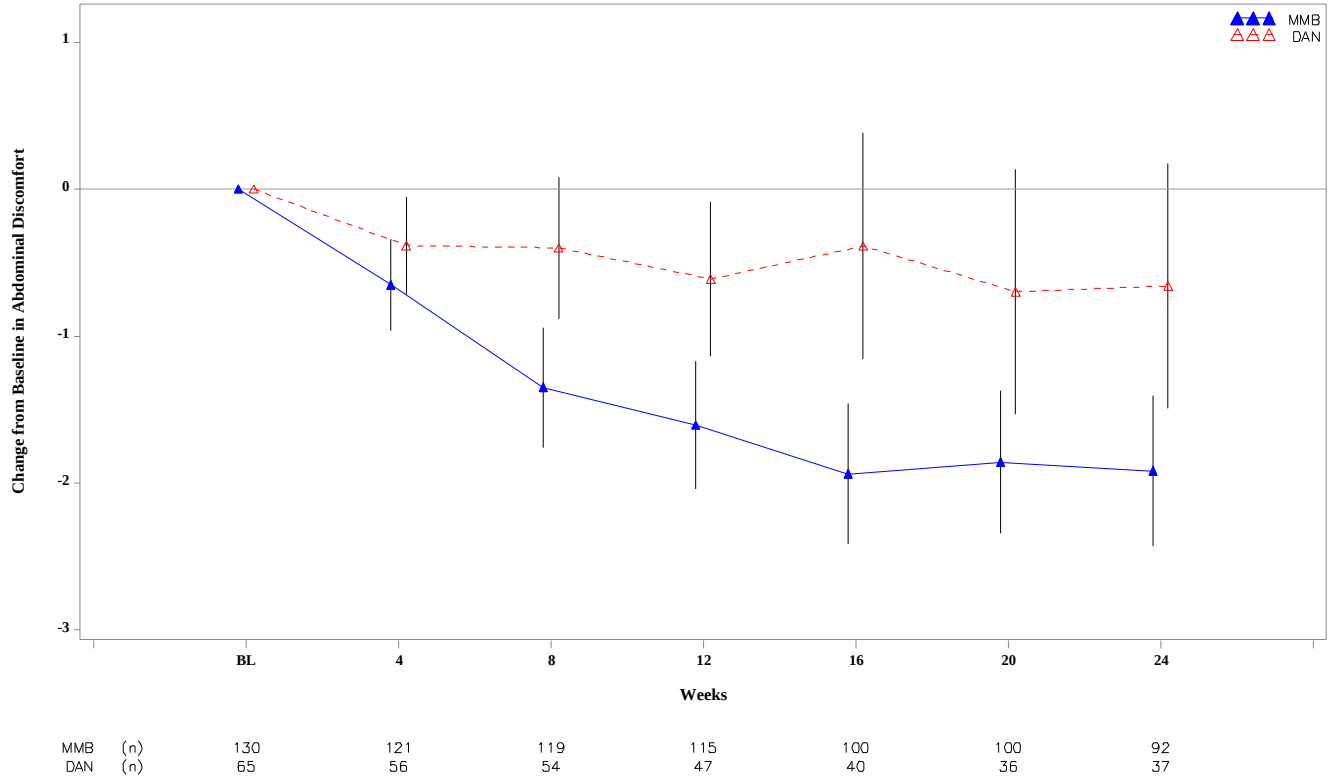
	MMB (N=130)	DAN (N=65)	Total (N=195)
Splenic Response Rate (SRR) at Week 24			
Responder, n(%)	51 (39.2%)	4 (6.2%)	55 (28.2%)
95% Exact CI [1]	39.23 (30.79, 48.18)	6.15 (1.70, 15.01)	
Difference (95% CI)			
Unstratified Exact [2]	33.08 (20.83, 43.12)		
Stratified CMH	33.05 (22.59, 43.51)		
p-value from stratified CMH test	<0.001		
Unadjusted Inverse Relative Risk (95% CI)	0.16 (0.06, 0.42)		
p-value [3]	<0.001		
Unadjusted Inverse Odds Ratio (95% CI)	0.10 (0.03, 0.30)		
p-value [3]	<0.001		
Unadjusted Absolute Risk Difference (95% CI)	0.33 (0.23, 0.43)		
Adjusted Inverse Relative Risk (95% CI) [4]	0.16 (0.06, 0.41)		
p-value [4]	<0.001		
Non-Responder, n(%)	79 (60.8%)	61 (93.8%)	140 (71.8%)
Missing baseline evaluation	0	0	0
Missing Week 24 visit evaluation	38 (29.2%)	28 (43.1%)	66 (33.8%)
Scan taken more than 10 days after the start of OL treatment	2 (1.5%)	0	2 (1.0%)
Subjects with differing modalities of spleen scan at baseline and week 24 visit	2 (1.5%)	0	2 (1.0%)
Subjects with <25% reduction or increased spleen volume	36 (27.7%)	33 (50.8%)	69 (35.4%)
Subjects with prohibited medication during RT period	5 (3.8%)	1 (1.5%)	6 (3.1%)

Notes: Splenic response rate (SRR) is defined as the proportion of subjects who have reduction in spleen volume of >= 25% from baseline at the end of Week 24. Results are based on central (or local, when central is not available) spleen volumetric assessment.
Imaging modality and assessment method (central or local) must match at baseline and Week 24. CMH = Cochran-Mantel-Haenszel.
[1] Exact binomial confidence interval. [2] 95% Exact CI is based on Clopper-Pearson method without stratification.
[3] p-values were from a Z-test.
[4] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, Baseline MFSAF TSS (<22, >=22), Baseline palpable spleen length below the left costal margin (<12cm, >=12cm) and Baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+) as covariates.

3.2 Symptomansprechen

GSK Oncology
Study SRA-MMB-301

Figure 2.0204: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Abdominal Discomfort (MFSAF)
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

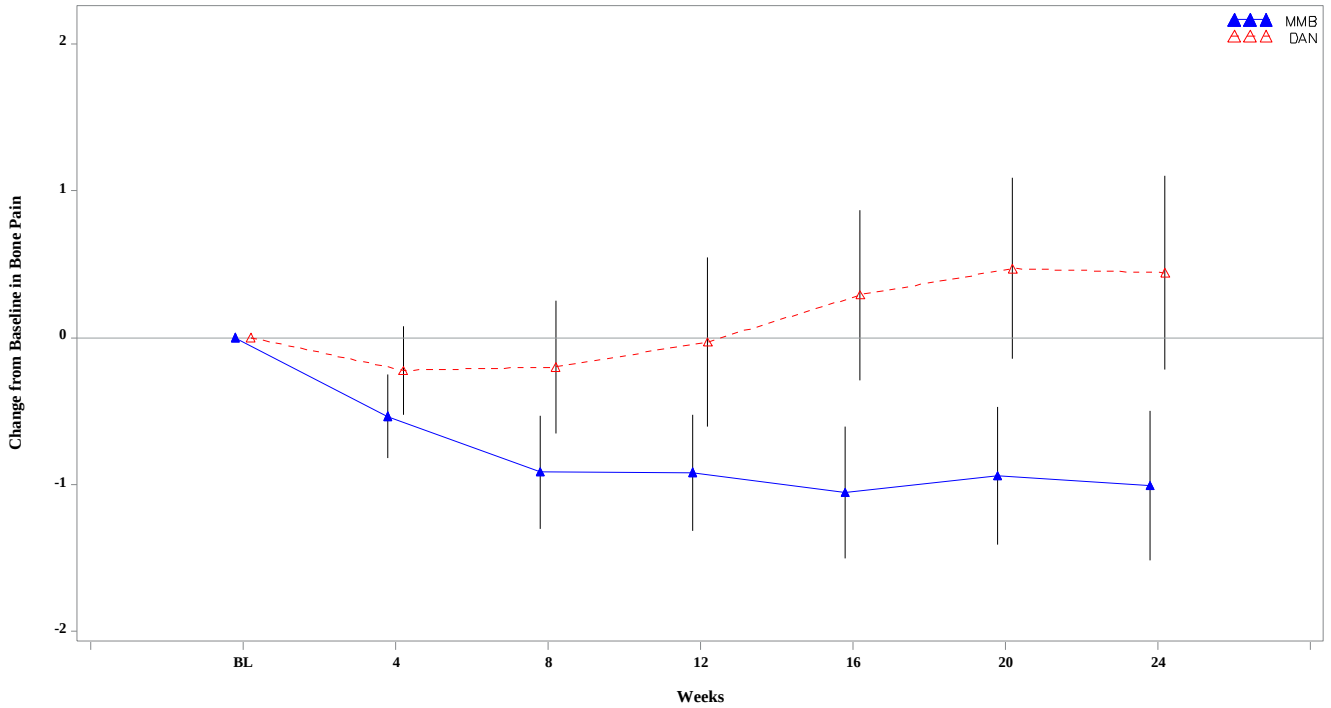


MMB	(n)	130	121	119	115	100	100	92
DAN	(n)	65	56	54	47	40	36	37

MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-tss-chg-gba.sas V.03.05 Output file: g-tss-chg-ad-gba.pdf 31AUG2023:15:26

Figure 2.0207: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Bone Pain (MFSAF)
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

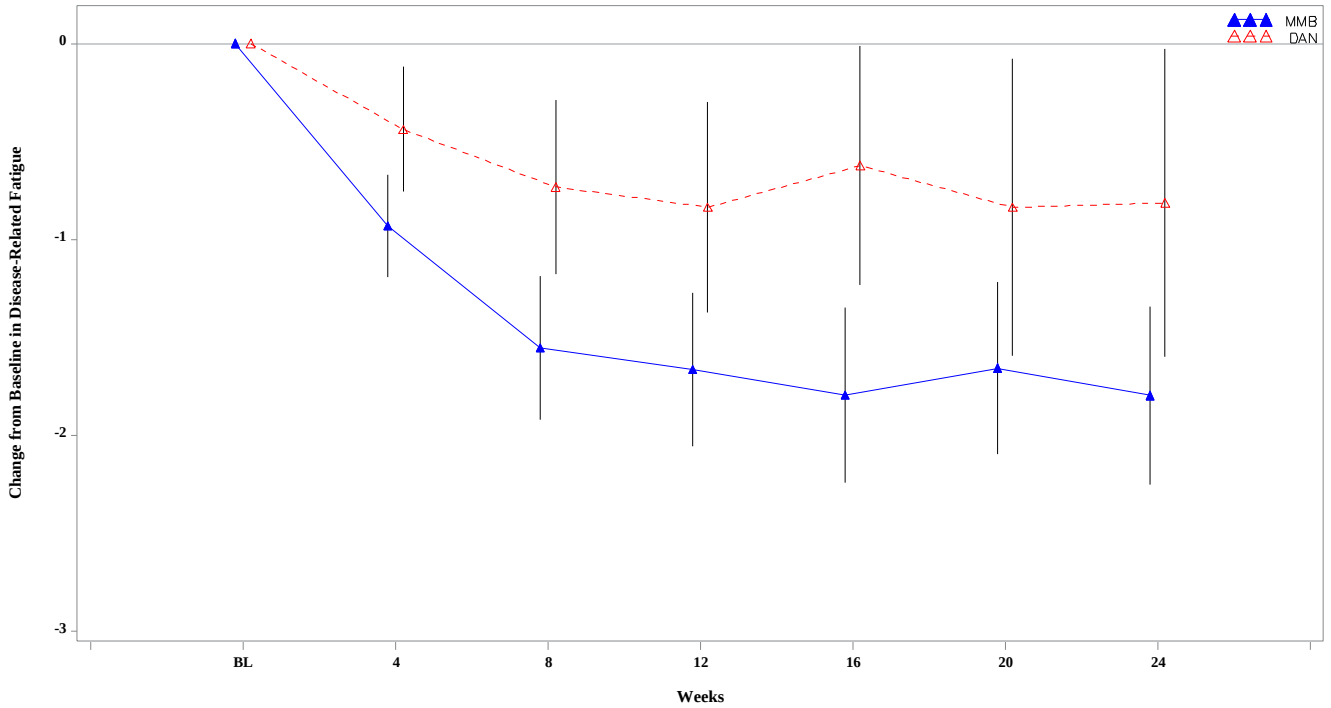


MMB	(n)	130	121	119	115	100	100	92
DAN	(n)	65	56	54	47	40	36	37

MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-tss-chg-gba.sas V.03.05 Output file: g-tss-chg-bone-gba.pdf 31AUG2023:15:26

Figure 2.0201: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Disease-Related Fatigue (MFSAF)
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

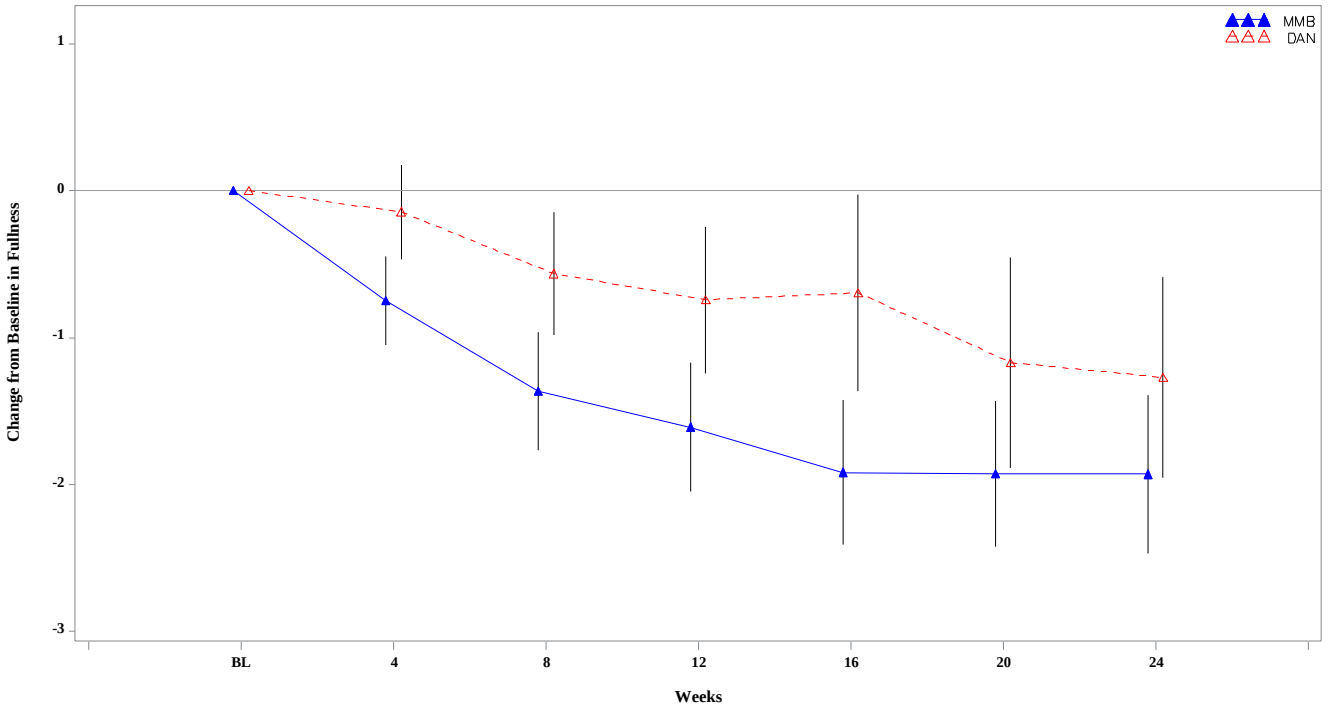


MMB	(n)	130	121	119	115	100	100	92
DAN	(n)	65	56	54	47	40	36	37

MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-tss-chg-gba.sas V.03.05 Output file: g-tss-chg-drf-gba.pdf 31AUG2023:15:26

Figure 2.0206: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Fullness (MFSAF)
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

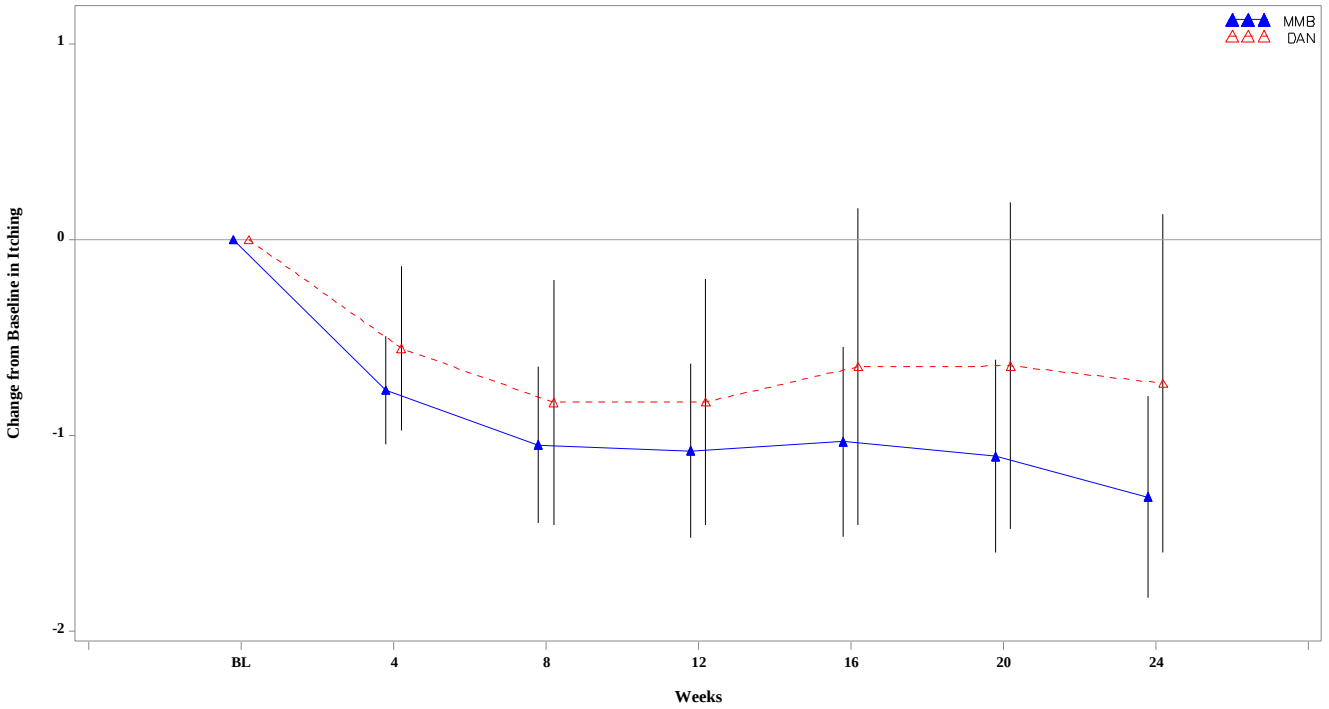


MMB	(n)	130	121	119	115	100	100	92
DAN	(n)	65	56	54	47	40	36	37

MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-tss-chg-gba.sas V.03.05 Output file: g-tss-chg-full-gba.pdf 31AUG2023:15:26

Figure 2.0203: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Itching (MFSAF)
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

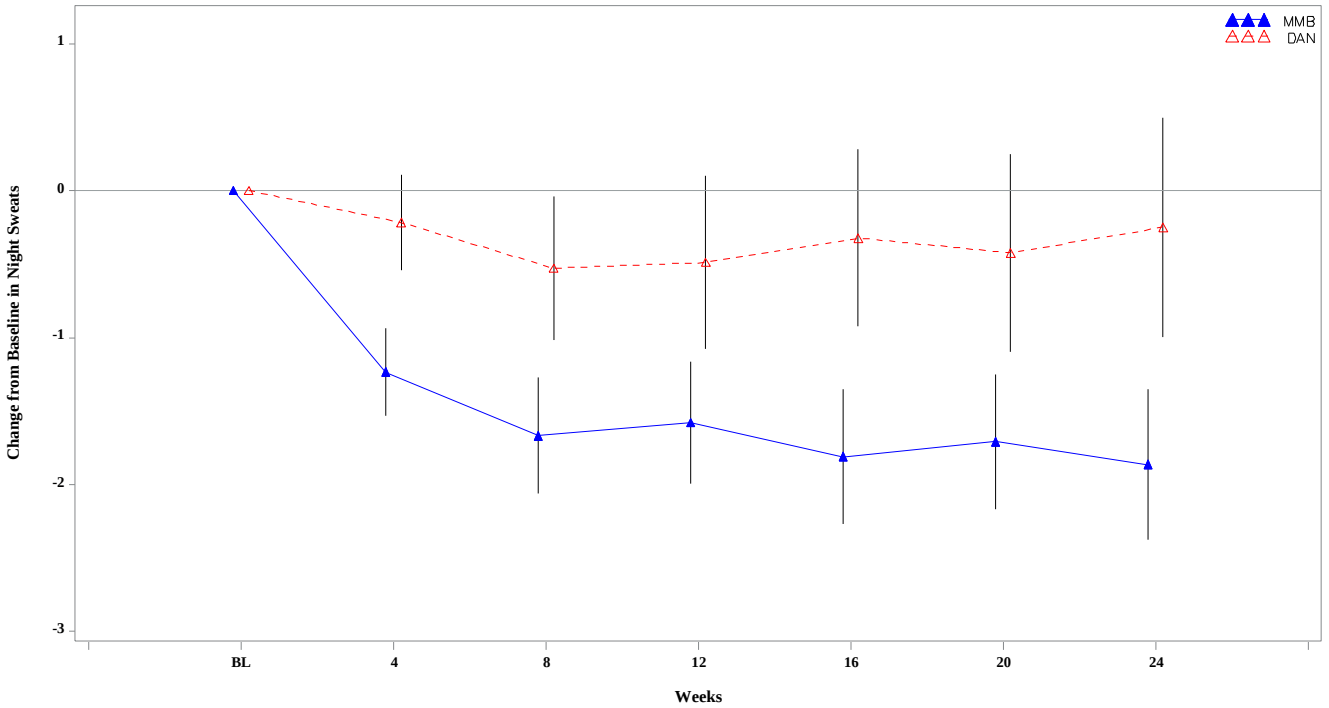


MMB	(n)	130	121	119	115	100	100	92
DAN	(n)	65	56	54	47	40	36	37

MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-tss-chg-gba.sas V.03.05 Output file: g-tss-chg-itch-gba.pdf 31AUG2023:15:26

Figure 2.0202: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Night Sweats (MFSAF)
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

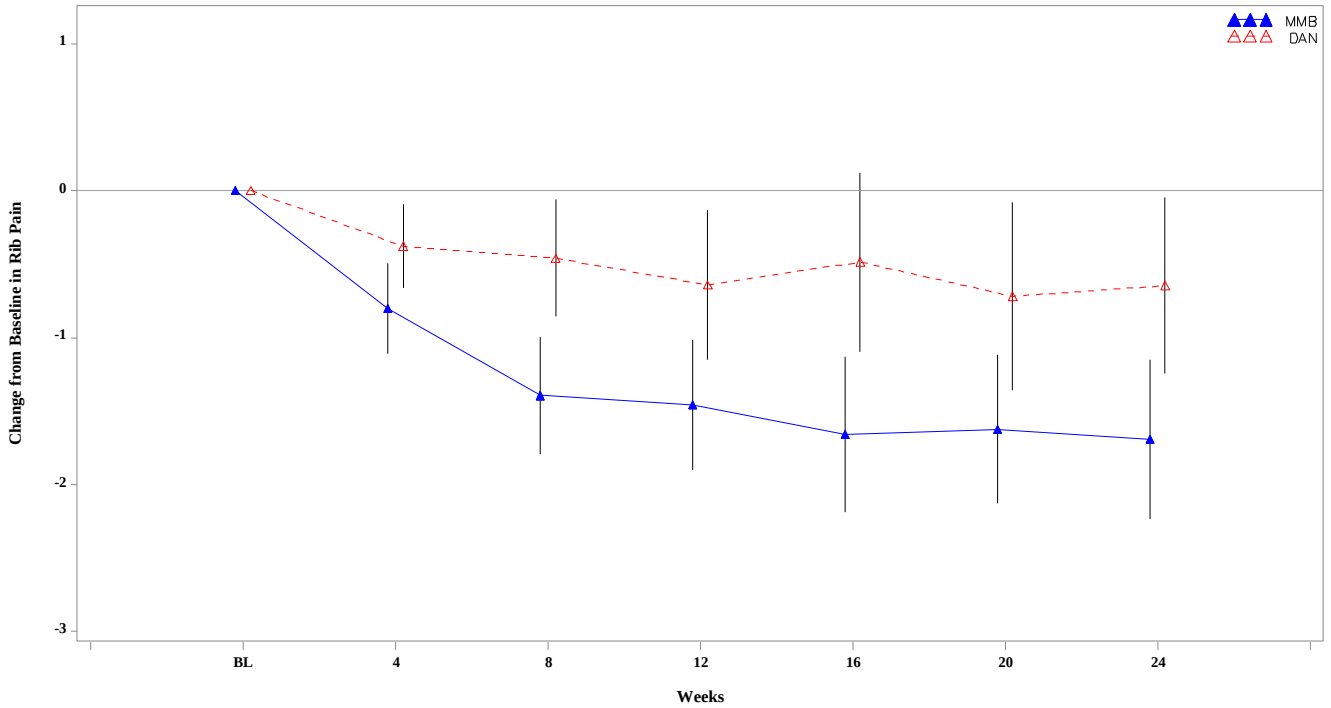


MMB	(n)	130	121	119	115	100	100	92
DAN	(n)	65	56	54	47	40	36	37

MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-tss-chg-gba.sas V.03.05 Output file: g-tss-chg-ns-gba.pdf 31AUG2023:15:26

Figure 2.0205: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Rib Pain (MFSAF)
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

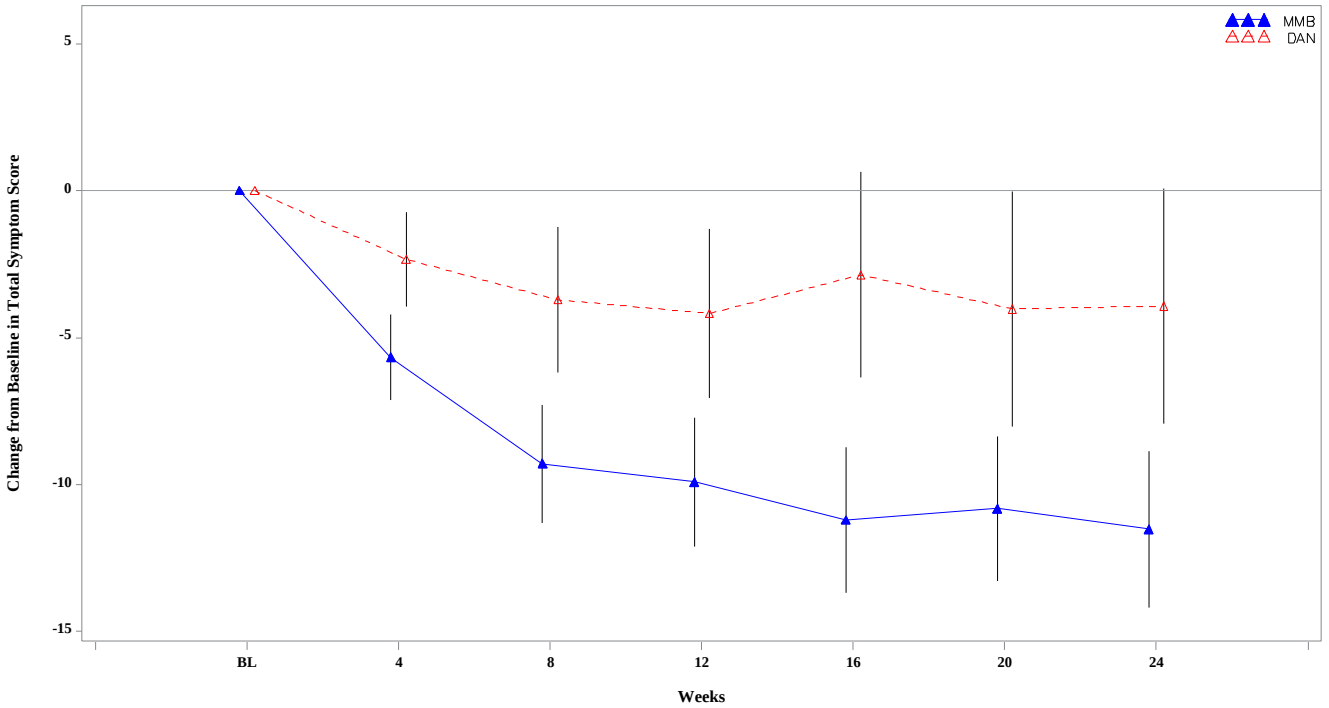


MMB	(n)	130	121	119	115	100	100	92
DAN	(n)	65	56	54	47	40	36	37

MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-tss-chg-gba.sas V.03.05 Output file: g-tss-chg-rib-gba.pdf 31AUG2023:15:26

Figure 2.0101: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Total Symptom Score (MFSAF)
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set



MMB	(n)	130	121	119	115	100	100	92
DAN	(n)	65	56	54	47	40	36	37

MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-tss-chg-gba.sas V.03.05 Output file: g-tss-chg-rt24-gba.pdf 31AUG2023:15:26

GSK Oncology

Study SRA-MMB-301

Table 2.0504: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Abdominal Discomfort

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Abdominal Discomfort Item Score			
Baseline			
n (%)	130 (100%)	65 (100%)	195 (100%)
Mean (SD)	4.41 (2.65)	3.97 (2.45)	4.26 (2.59)
Median	4.62	4.14	4.33
Q1, Q3	2.33, 6.29	1.86, 5.86	2.29, 6.29
Min, Max	0.0, 10.0	0.0, 8.1	0.0, 10.0
Return Rate (%)	100%	100%	
Number of Subjects in Risk	130	65	
Return Rate in Risk (%)	100%	100%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.0504: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Abdominal Discomfort

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 4			
n (%)	121 (93.1%)	56 (86.2%)	177 (90.8%)
Mean (SD)	3.71 (2.34)	3.58 (2.42)	3.67 (2.36)
Median	3.36	3.60	3.48
Q1, Q3	2.18, 5.54	1.36, 4.89	1.93, 5.18
Min, Max	0.0, 8.6	0.0, 8.4	0.0, 8.6
Change from Baseline			
n (%)	121 (93.1%)	56 (86.2%)	177 (90.8%)
Mean (SD)	-0.65 (1.72)	-0.38 (1.24)	-0.57 (1.59)
Median	-0.50	-0.23	-0.39
Q1, Q3	-1.58, 0.25	-1.25, 0.45	-1.43, 0.35
Min, Max	-5.4, 5.1	-3.4, 2.8	-5.4, 5.1
Least Squares Mean (SE) [1]	-0.58 (0.15)	-0.34 (0.21)	
95% CI [1]	-0.87, -0.30	-0.75, 0.07	
Least Squares Mean Difference (SE) [1]	-0.25 (0.25)		
95% CI [1]	-0.73, 0.24		
p-value [2]	0.31		
Corrected Hedges' g (95% CI)	-0.155 (-0.472, 0.162)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t_tss_chg_rt24_gba.sas V.03.05 Output file: t-c-ad-g.pdf 13SEP2023: 8:35

Table 2.0504: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Abdominal Discomfort

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	114 (87.7%)	52 (80.0%)	166 (85.1%)
Mean (SD)	5.61 (117.75)	11.08 (128.24)	7.33 (120.77)
Median	-14.21	-5.21	-12.46
Q1, Q3	-36.00, 6.82	-33.34, 12.45	-34.91, 9.85
Min, Max	-100.0, 770.0	-100.0, 807.4	-100.0, 807.4
Return Rate (%)	93%	86%	
Number of Subjects in Risk	130	65	
Return Rate in Risk (%)	93%	86%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
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Table 2.0504: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Abdominal Discomfort

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 8			
n (%)	119 (91.5%)	54 (83.1%)	173 (88.7%)
Mean (SD)	3.16 (2.36)	3.47 (2.34)	3.26 (2.35)
Median	2.86	3.49	2.89
Q1, Q3	1.19, 4.83	1.86, 5.18	1.39, 4.90
Min, Max	0.0, 8.8	0.0, 9.1	0.0, 9.1
Change from Baseline			
n (%)	119 (91.5%)	54 (83.1%)	173 (88.7%)
Mean (SD)	-1.35 (2.24)	-0.40 (1.76)	-1.05 (2.14)
Median	-0.79	-0.24	-0.64
Q1, Q3	-2.62, 0.00	-1.37, 0.62	-2.54, 0.32
Min, Max	-8.0, 4.6	-3.8, 3.7	-8.0, 4.6
Least Squares Mean (SE) [1]	-1.15 (0.19)	-0.41 (0.28)	
95% CI [1]	-1.53, -0.76	-0.97, 0.14	
Least Squares Mean Difference (SE) [1]	-0.74 (0.34)		
95% CI [1]	-1.40, -0.07		
p-value [2]	0.029		
Corrected Hedges' g (95% CI)	-0.348 (-0.672, -0.024)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t_tss_chg_rt24_gba.sas V.03.05 Output file: t-c-ad-g.pdf 13SEP2023: 8:35

Table 2.0504: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Abdominal Discomfort

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	113 (86.9%)	51 (78.5%)	164 (84.1%)
Mean (SD)	-15.03 (133.24)	22.78 (185.20)	-3.27 (151.75)
Median	-25.71	-6.99	-23.28
Q1, Q3	-58.18, -2.13	-41.15, 18.55	-51.56, 7.84
Min, Max	-100.0, 1287.5	-100.0, 1138.5	-100.0, 1287.5
Return Rate (%)	92%	83%	
Number of Subjects in Risk	129	63	
Return Rate in Risk (%)	92%	86%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t_tss_chg_rt24_gba.sas V.03.05 Output file: t-c-ad-g.pdf 13SEP2023: 8:35

Table 2.0504: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Abdominal Discomfort

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 12			
n (%)	115 (88.5%)	47 (72.3%)	162 (83.1%)
Mean (SD)	3.01 (2.19)	3.10 (2.20)	3.03 (2.18)
Median	2.70	3.11	2.77
Q1, Q3	1.18, 4.71	1.27, 4.14	1.19, 4.62
Min, Max	0.0, 8.7	0.0, 10.0	0.0, 10.0
Change from Baseline			
n (%)	115 (88.5%)	47 (72.3%)	162 (83.1%)
Mean (SD)	-1.60 (2.36)	-0.61 (1.80)	-1.32 (2.25)
Median	-0.93	-0.32	-0.83
Q1, Q3	-3.11, 0.00	-1.71, 0.67	-2.67, 0.19
Min, Max	-7.6, 2.9	-5.1, 3.2	-7.6, 3.2
Least Squares Mean (SE) [1]	-1.33 (0.20)	-0.62 (0.29)	
95% CI [1]	-1.72, -0.94	-1.19, -0.04	
Least Squares Mean Difference (SE) [1]	-0.72 (0.35)		
95% CI [1]	-1.40, -0.03		
p-value [2]	0.040		
Corrected Hedges' g (95% CI)	-0.341 (-0.682, 0.001)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t_tss_chg_rt24_gba.sas V.03.05 Output file: t-c-ad-g.pdf 13SEP2023: 8:35

Table 2.0504: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Abdominal Discomfort

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	110 (84.6%)	44 (67.7%)	154 (79.0%)
Mean (SD)	-27.25 (50.72)	8.51 (108.15)	-17.03 (73.37)
Median	-23.10	-13.58	-21.67
Q1, Q3	-65.63, -3.08	-41.60, 23.81	-62.14, 5.03
Min, Max	-100.0, 212.5	-100.0, 574.1	-100.0, 574.1
Return Rate (%)	88%	72%	
Number of Subjects in Risk	123	53	
Return Rate in Risk (%)	93%	89%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t_tss_chg_rt24_gba.sas V.03.05 Output file: t-c-ad-g.pdf 13SEP2023: 8:35

Table 2.0504: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Abdominal Discomfort

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 16			
n (%)	100 (76.9%)	40 (61.5%)	140 (71.8%)
Mean (SD)	2.66 (2.08)	3.32 (2.31)	2.85 (2.16)
Median	2.31	3.11	2.52
Q1, Q3	0.98, 4.03	1.93, 4.48	1.00, 4.29
Min, Max	0.0, 9.0	0.0, 10.0	0.0, 10.0
Change from Baseline			
n (%)	100 (76.9%)	40 (61.5%)	140 (71.8%)
Mean (SD)	-1.94 (2.41)	-0.39 (2.40)	-1.49 (2.50)
Median	-1.38	-0.36	-1.12
Q1, Q3	-3.68, 0.00	-1.71, 0.80	-3.03, 0.11
Min, Max	-7.3, 3.5	-5.7, 5.0	-7.3, 5.0
Least Squares Mean (SE) [1]	-1.45 (0.21)	-0.36 (0.31)	
95% CI [1]	-1.87, -1.03	-0.98, 0.25	
Least Squares Mean Difference (SE) [1]	-1.08 (0.37)		
95% CI [1]	-1.82, -0.35		
p-value [2]	0.004		
Corrected Hedges' g (95% CI)	-0.516 (-0.888, -0.144)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t_tss_chg_rt24_gba.sas V.03.05 Output file: t-c-ad-g.pdf 13SEP2023: 8:35

Table 2.0504: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Abdominal Discomfort

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	95 (73.1%)	38 (58.5%)	133 (68.2%)
Mean (SD)	-33.24 (54.04)	41.75 (200.43)	-11.81 (120.40)
Median	-37.16	-14.26	-33.33
Q1, Q3	-70.30, -8.33	-45.00, 50.00	-65.43, 2.64
Min, Max	-100.0, 206.3	-100.0, 1030.8	-100.0, 1030.8
Return Rate (%)	77%	62%	
Number of Subjects in Risk	113	48	
Return Rate in Risk (%)	88%	83%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t_tss_chg_rt24_gba.sas V.03.05 Output file: t-c-ad-g.pdf 13SEP2023: 8:35

Table 2.0504: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Abdominal Discomfort

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 20			
n (%)	100 (76.9%)	36 (55.4%)	136 (69.7%)
Mean (SD)	2.69 (2.10)	3.17 (2.15)	2.82 (2.11)
Median	2.23	3.04	2.45
Q1, Q3	1.00, 4.00	1.86, 4.54	1.04, 4.09
Min, Max	0.0, 9.6	0.0, 10.0	0.0, 10.0
Change from Baseline			
n (%)	100 (76.9%)	36 (55.4%)	136 (69.7%)
Mean (SD)	-1.86 (2.44)	-0.70 (2.47)	-1.55 (2.49)
Median	-1.44	-0.52	-1.19
Q1, Q3	-3.14, -0.16	-2.80, 0.73	-3.08, 0.21
Min, Max	-9.2, 3.8	-6.1, 4.3	-9.2, 4.3
Least Squares Mean (SE) [1]	-1.49 (0.22)	-0.31 (0.33)	
95% CI [1]	-1.93, -1.05	-0.97, 0.35	
Least Squares Mean Difference (SE) [1]	-1.18 (0.40)		
95% CI [1]	-1.96, -0.40		
p-value [2]	0.003		
Corrected Hedges' g (95% CI)	-0.538 (-0.925, -0.152)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Study SRA-MMB-301

Table 2.0504: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Abdominal Discomfort

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	95 (73.1%)	35 (53.8%)	130 (66.7%)
Mean (SD)	-33.22 (51.85)	49.89 (289.50)	-10.85 (159.43)
Median	-37.78	-14.29	-36.04
Q1, Q3	-70.04, -10.44	-57.87, 36.96	-64.66, 3.85
Min, Max	-100.0, 187.5	-100.0, 1504.2	-100.0, 1504.2
Return Rate (%)	77%	55%	
Number of Subjects in Risk	106	42	
Return Rate in Risk (%)	94%	86%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.0504: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Abdominal Discomfort

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 24			
n (%)	92 (70.8%)	37 (56.9%)	129 (66.2%)
Mean (SD)	2.70 (2.14)	3.18 (2.20)	2.84 (2.16)
Median	2.20	3.00	2.60
Q1, Q3	1.02, 4.26	1.85, 4.18	1.08, 4.26
Min, Max	0.0, 9.0	0.0, 10.0	0.0, 10.0
Change from Baseline			
n (%)	92 (70.8%)	37 (56.9%)	129 (66.2%)
Mean (SD)	-1.92 (2.47)	-0.66 (2.51)	-1.56 (2.53)
Median	-1.47	-0.50	-1.25
Q1, Q3	-3.10, 0.00	-2.33, 0.39	-2.97, 0.09
Min, Max	-8.7, 3.1	-5.5, 5.4	-8.7, 5.4
Least Squares Mean (SE) [1]	-1.43 (0.23)	-0.32 (0.34)	
95% CI [1]	-1.88, -0.98	-0.99, 0.35	
Least Squares Mean Difference (SE) [1]	-1.11 (0.40)		
95% CI [1]	-1.91, -0.31		
p-value [2]	0.007		
Corrected Hedges' g (95% CI)	-0.512 (-0.898, -0.125)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
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Study SRA-MMB-301

Table 2.0504: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Abdominal Discomfort

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	87 (66.9%)	35 (53.8%)	122 (62.6%)
Mean (SD)	-33.97 (55.42)	37.45 (325.62)	-13.48 (181.74)
Median	-39.58	-15.26	-35.09
Q1, Q3	-77.14, -2.27	-52.79, 20.16	-67.98, 0.86
Min, Max	-100.0, 230.6	-100.0, 1875.0	-100.0, 1875.0
Return Rate (%)	71%	57%	
Number of Subjects in Risk	99	39	
Return Rate in Risk (%)	93%	95%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

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Study SRA-MMB-301

Table 2.0507: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Bone Pain

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Bone Pain Item Score			
Baseline			
n (%)	130 (100%)	65 (100%)	195 (100%)
Mean (SD)	3.24 (2.65)	2.90 (2.36)	3.12 (2.56)
Median	2.85	2.83	2.83
Q1, Q3	1.17, 5.00	0.71, 4.29	1.00, 4.86
Min, Max	0.0, 9.3	0.0, 8.9	0.0, 9.3
Return Rate (%)	100%	100%	
Number of Subjects in Risk	130	65	
Return Rate in Risk (%)	100%	100%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.0507: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Bone Pain

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 4			
n (%)	121 (93.1%)	56 (86.2%)	177 (90.8%)
Mean (SD)	2.64 (2.44)	2.61 (2.33)	2.63 (2.40)
Median	2.14	2.50	2.14
Q1, Q3	0.08, 4.43	0.30, 4.07	0.12, 4.32
Min, Max	0.0, 9.5	0.0, 8.6	0.0, 9.5
Change from Baseline			
n (%)	121 (93.1%)	56 (86.2%)	177 (90.8%)
Mean (SD)	-0.54 (1.57)	-0.22 (1.12)	-0.44 (1.45)
Median	-0.11	0.00	-0.07
Q1, Q3	-1.25, 0.14	-0.74, 0.41	-1.04, 0.26
Min, Max	-5.1, 4.0	-3.1, 3.0	-5.1, 4.0
Least Squares Mean (SE) [1]	-0.59 (0.14)	-0.20 (0.19)	
95% CI [1]	-0.86, -0.32	-0.58, 0.18	
Least Squares Mean Difference (SE) [1]	-0.39 (0.23)		
95% CI [1]	-0.84, 0.06		
p-value [2]	0.090		
Corrected Hedges' g (95% CI)	-0.262 (-0.580, 0.055)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
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Study SRA-MMB-301

Table 2.0507: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Bone Pain

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	98 (75.4%)	48 (73.8%)	146 (74.9%)
Mean (SD)	-2.09 (136.12)	-8.62 (58.47)	-4.24 (116.25)
Median	-22.16	-5.63	-11.56
Q1, Q3	-47.92, 9.80	-46.09, 12.23	-47.92, 11.46
Min, Max	-100.0, 1175.0	-100.0, 159.3	-100.0, 1175.0
Return Rate (%)	93%	86%	
Number of Subjects in Risk	130	65	
Return Rate in Risk (%)	93%	86%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.0507: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Bone Pain

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 8			
n (%)	119 (91.5%)	54 (83.1%)	173 (88.7%)
Mean (SD)	2.31 (2.30)	2.75 (2.43)	2.45 (2.34)
Median	1.74	2.30	2.00
Q1, Q3	0.09, 3.79	0.60, 4.36	0.14, 3.93
Min, Max	0.0, 8.2	0.0, 9.4	0.0, 9.4
Change from Baseline			
n (%)	119 (91.5%)	54 (83.1%)	173 (88.7%)
Mean (SD)	-0.91 (2.12)	-0.20 (1.65)	-0.69 (2.01)
Median	-0.46	0.04	-0.27
Q1, Q3	-2.25, 0.15	-1.18, 0.64	-2.00, 0.32
Min, Max	-6.6, 4.7	-4.7, 4.0	-6.6, 4.7
Least Squares Mean (SE) [1]	-0.87 (0.18)	-0.06 (0.26)	
95% CI [1]	-1.22, -0.51	-0.57, 0.45	
Least Squares Mean Difference (SE) [1]	-0.80 (0.31)		
95% CI [1]	-1.41, -0.20		
p-value [2]	0.010		
Corrected Hedges' g (95% CI)	-0.415 (-0.739, -0.090)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Table 2.0507: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Bone Pain

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	98 (75.4%)	48 (73.8%)	146 (74.9%)
Mean (SD)	-2.58 (211.13)	13.44 (107.25)	2.69 (183.31)
Median	-33.19	3.75	-19.90
Q1, Q3	-69.23, 6.40	-44.56, 35.80	-66.67, 19.07
Min, Max	-100.0, 1948.1	-100.0, 496.3	-100.0, 1948.1
Return Rate (%)	92%	83%	
Number of Subjects in Risk	129	63	
Return Rate in Risk (%)	92%	86%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Table 2.0507: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Bone Pain

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 12			
n (%)	115 (88.5%)	47 (72.3%)	162 (83.1%)
Mean (SD)	2.42 (2.39)	3.11 (2.59)	2.62 (2.46)
Median	2.04	2.54	2.14
Q1, Q3	0.00, 4.00	1.00, 4.88	0.05, 4.07
Min, Max	0.0, 8.6	0.0, 10.0	0.0, 10.0
Change from Baseline			
n (%)	115 (88.5%)	47 (72.3%)	162 (83.1%)
Mean (SD)	-0.92 (2.14)	-0.03 (1.97)	-0.66 (2.13)
Median	-0.54	0.03	-0.25
Q1, Q3	-1.93, 0.18	-1.50, 1.07	-1.78, 0.45
Min, Max	-6.6, 5.1	-4.6, 5.4	-6.6, 5.4
Least Squares Mean (SE) [1]	-0.90 (0.19)	0.13 (0.27)	
95% CI [1]	-1.27, -0.53	-0.40, 0.67	
Least Squares Mean Difference (SE) [1]	-1.03 (0.33)		
95% CI [1]	-1.67, -0.39		
p-value [2]	0.002		
Corrected Hedges' g (95% CI)	-0.521 (-0.865, -0.177)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Table 2.0507: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Bone Pain

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	98 (75.4%)	42 (64.6%)	140 (71.8%)
Mean (SD)	-9.88 (126.69)	21.82 (102.23)	-0.37 (120.40)
Median	-25.00	2.27	-19.52
Q1, Q3	-77.00, 10.80	-42.86, 41.96	-65.01, 18.99
Min, Max	-100.0, 1020.0	-100.0, 375.0	-100.0, 1020.0
Return Rate (%)	88%	72%	
Number of Subjects in Risk	123	53	
Return Rate in Risk (%)	93%	89%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Table 2.0507: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Bone Pain

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 16			
n (%)	100 (76.9%)	40 (61.5%)	140 (71.8%)
Mean (SD)	2.37 (2.30)	3.45 (2.75)	2.67 (2.48)
Median	1.98	2.89	2.23
Q1, Q3	0.14, 4.00	1.15, 5.77	0.34, 4.13
Min, Max	0.0, 9.9	0.0, 10.0	0.0, 10.0
Change from Baseline			
n (%)	100 (76.9%)	40 (61.5%)	140 (71.8%)
Mean (SD)	-1.05 (2.25)	0.29 (1.81)	-0.67 (2.21)
Median	-0.59	0.72	-0.10
Q1, Q3	-2.47, 0.20	-0.26, 1.54	-1.85, 0.79
Min, Max	-6.7, 3.7	-4.6, 3.4	-6.7, 3.7
Least Squares Mean (SE) [1]	-0.86 (0.19)	0.15 (0.28)	
95% CI [1]	-1.24, -0.48	-0.41, 0.71	
Least Squares Mean Difference (SE) [1]	-1.01 (0.34)		
95% CI [1]	-1.68, -0.34		
p-value [2]	0.003		
Corrected Hedges' g (95% CI)	-0.531 (-0.903, -0.159)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t_tss_chg_rt24_gba.sas V.03.05 Output file: t-c-bone-g.pdf 13SEP2023: 8:35

Table 2.0507: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Bone Pain

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	86 (66.2%)	36 (55.4%)	122 (62.6%)
Mean (SD)	-16.17 (85.51)	34.88 (108.31)	-1.10 (95.27)
Median	-27.13	28.86	-15.59
Q1, Q3	-75.86, 4.67	-23.46, 55.34	-68.18, 29.63
Min, Max	-100.0, 300.0	-100.0, 522.2	-100.0, 522.2
Return Rate (%)	77%	62%	
Number of Subjects in Risk	113	48	
Return Rate in Risk (%)	88%	83%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Table 2.0507: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Bone Pain

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 20			
n (%)	100 (76.9%)	36 (55.4%)	136 (69.7%)
Mean (SD)	2.37 (2.29)	3.59 (2.91)	2.69 (2.52)
Median	1.89	3.04	2.14
Q1, Q3	0.04, 3.89	1.00, 6.08	0.16, 4.26
Min, Max	0.0, 9.1	0.0, 10.0	0.0, 10.0
Change from Baseline			
n (%)	100 (76.9%)	36 (55.4%)	136 (69.7%)
Mean (SD)	-0.94 (2.37)	0.47 (1.82)	-0.57 (2.32)
Median	-0.46	0.67	-0.11
Q1, Q3	-2.32, 0.07	-0.53, 1.89	-1.57, 0.84
Min, Max	-7.6, 4.5	-4.1, 3.2	-7.6, 4.5
Least Squares Mean (SE) [1]	-0.88 (0.20)	0.38 (0.31)	
95% CI [1]	-1.28, -0.47	-0.22, 0.98	
Least Squares Mean Difference (SE) [1]	-1.26 (0.36)		
95% CI [1]	-1.97, -0.54		
p-value [2]	<0.001		
Corrected Hedges' g (95% CI)	-0.630 (-1.018, -0.242)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Table 2.0507: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Bone Pain

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	85 (65.4%)	32 (49.2%)	117 (60.0%)
Mean (SD)	-10.94 (88.93)	37.96 (108.48)	2.43 (96.70)
Median	-22.79	30.79	-13.10
Q1, Q3	-74.00, 9.20	-26.42, 76.26	-68.79, 43.52
Min, Max	-100.0, 324.7	-100.0, 483.3	-100.0, 483.3
Return Rate (%)	77%	55%	
Number of Subjects in Risk	106	42	
Return Rate in Risk (%)	94%	86%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Table 2.0507: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Bone Pain

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 24			
n (%)	92 (70.8%)	37 (56.9%)	129 (66.2%)
Mean (SD)	2.50 (2.27)	3.59 (3.03)	2.81 (2.55)
Median	2.31	3.00	2.43
Q1, Q3	0.06, 4.02	0.96, 5.32	0.29, 4.36
Min, Max	0.0, 9.0	0.0, 10.0	0.0, 10.0
Change from Baseline			
n (%)	92 (70.8%)	37 (56.9%)	129 (66.2%)
Mean (SD)	-1.01 (2.45)	0.44 (1.97)	-0.59 (2.40)
Median	-0.50	0.21	-0.14
Q1, Q3	-2.50, 0.37	-0.37, 1.37	-1.87, 0.79
Min, Max	-7.3, 4.0	-4.3, 5.2	-7.3, 5.2
Least Squares Mean (SE) [1]	-0.84 (0.21)	0.35 (0.31)	
95% CI [1]	-1.26, -0.43	-0.27, 0.97	
Least Squares Mean Difference (SE) [1]	-1.19 (0.37)		
95% CI [1]	-1.92, -0.46		
p-value [2]	0.002		
Corrected Hedges' g (95% CI)	-0.596 (-0.985, -0.208)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Table 2.0507: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Bone Pain

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	79 (60.8%)	33 (50.8%)	112 (57.4%)
Mean (SD)	-2.50 (131.82)	34.17 (99.87)	8.30 (123.96)
Median	-28.68	12.00	-11.33
Q1, Q3	-74.36, 11.63	-11.76, 60.71	-66.34, 35.27
Min, Max	-100.0, 896.2	-100.0, 366.7	-100.0, 896.2
Return Rate (%)	71%	57%	
Number of Subjects in Risk	99	39	
Return Rate in Risk (%)	93%	95%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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GSK Oncology

Study SRA-MMB-301

Table 2.0501: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Disease-Related Fatigue

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Fatigue Item Score			
Baseline			
n (%)	130 (100%)	65 (100%)	195 (100%)
Mean (SD)	6.20 (2.14)	5.77 (2.08)	6.06 (2.13)
Median	6.38	5.86	6.17
Q1, Q3	4.71, 7.86	4.57, 7.29	4.57, 7.83
Min, Max	0.9, 10.0	1.0, 9.3	0.9, 10.0
Return Rate (%)	100%	100%	
Number of Subjects in Risk	130	65	
Return Rate in Risk (%)	100%	100%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

GSK Oncology

Study SRA-MMB-301

Table 2.0501: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Disease-Related Fatigue

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 4			
n (%)	121 (93.1%)	56 (86.2%)	177 (90.8%)
Mean (SD)	5.12 (2.20)	5.24 (2.37)	5.16 (2.25)
Median	5.11	4.95	5.11
Q1, Q3	3.71, 6.78	3.32, 7.56	3.48, 7.07
Min, Max	0.1, 10.0	1.0, 9.6	0.1, 10.0
Change from Baseline			
n (%)	121 (93.1%)	56 (86.2%)	177 (90.8%)
Mean (SD)	-0.93 (1.46)	-0.44 (1.19)	-0.77 (1.39)
Median	-0.85	-0.36	-0.79
Q1, Q3	-1.69, 0.07	-1.29, 0.29	-1.46, 0.19
Min, Max	-6.2, 2.2	-3.1, 2.8	-6.2, 2.8
Least Squares Mean (SE) [1]	-0.97 (0.13)	-0.49 (0.19)	
95% CI [1]	-1.23, -0.71	-0.87, -0.12	
Least Squares Mean Difference (SE) [1]	-0.47 (0.22)		
95% CI [1]	-0.91, -0.04		
p-value [2]	0.034		
Corrected Hedges' g (95% CI)	-0.329 (-0.647, -0.010)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

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Study SRA-MMB-301

Table 2.0501: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Disease-Related Fatigue

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	121 (93.1%)	56 (86.2%)	177 (90.8%)
Mean (SD)	-14.30 (29.22)	-8.13 (24.36)	-12.35 (27.85)
Median	-13.08	-6.67	-12.22
Q1, Q3	-28.70, 1.01	-25.43, 4.33	-27.37, 2.57
Min, Max	-94.2, 88.3	-58.3, 57.4	-94.2, 88.3
Return Rate (%)	93%	86%	
Number of Subjects in Risk	130	65	
Return Rate in Risk (%)	93%	86%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.0501: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Disease-Related Fatigue
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 8			
n (%)	119 (91.5%)	54 (83.1%)	173 (88.7%)
Mean (SD)	4.66 (2.32)	4.81 (2.44)	4.71 (2.35)
Median	4.46	4.72	4.59
Q1, Q3	3.07, 6.30	3.04, 7.04	3.07, 6.64
Min, Max	0.0, 9.8	0.0, 9.2	0.0, 9.8
Change from Baseline			
n (%)	119 (91.5%)	54 (83.1%)	173 (88.7%)
Mean (SD)	-1.55 (2.02)	-0.73 (1.63)	-1.30 (1.94)
Median	-1.23	-0.48	-1.07
Q1, Q3	-2.99, 0.00	-1.98, 0.50	-2.51, 0.15
Min, Max	-7.5, 2.7	-4.8, 2.3	-7.5, 2.7
Least Squares Mean (SE) [1]	-1.50 (0.18)	-0.76 (0.25)	
95% CI [1]	-1.84, -1.15	-1.26, -0.26	
Least Squares Mean Difference (SE) [1]	-0.73 (0.30)		
95% CI [1]	-1.33, -0.14		
p-value [2]	0.016		
Corrected Hedges' g (95% CI)	-0.385 (-0.709, -0.060)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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GSK Oncology

Study SRA-MMB-301

Table 2.0501: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Disease-Related Fatigue

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	119 (91.5%)	54 (83.1%)	173 (88.7%)
Mean (SD)	-23.11 (34.19)	-13.56 (32.55)	-20.13 (33.88)
Median	-22.22	-5.83	-20.75
Q1, Q3	-45.00, 0.00	-33.84, 10.94	-41.58, 1.85
Min, Max	-100.0, 65.2	-100.0, 47.3	-100.0, 65.2
Return Rate (%)	92%	83%	
Number of Subjects in Risk	129	63	
Return Rate in Risk (%)	92%	86%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.0501: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Disease-Related Fatigue
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 12			
n (%)	115 (88.5%)	47 (72.3%)	162 (83.1%)
Mean (SD)	4.49 (2.30)	4.59 (2.40)	4.52 (2.32)
Median	4.43	4.29	4.38
Q1, Q3	2.93, 5.89	2.64, 6.96	2.93, 6.13
Min, Max	0.0, 9.9	0.0, 10.0	0.0, 10.0
Change from Baseline			
n (%)	115 (88.5%)	47 (72.3%)	162 (83.1%)
Mean (SD)	-1.66 (2.12)	-0.83 (1.83)	-1.42 (2.07)
Median	-1.29	-0.74	-1.01
Q1, Q3	-3.16, -0.06	-2.15, 0.41	-2.77, 0.11
Min, Max	-7.8, 2.2	-5.1, 3.0	-7.8, 3.0
Least Squares Mean (SE) [1]	-1.53 (0.19)	-0.85 (0.27)	
95% CI [1]	-1.90, -1.16	-1.39, -0.31	
Least Squares Mean Difference (SE) [1]	-0.68 (0.33)		
95% CI [1]	-1.33, -0.04		
p-value [2]	0.038		
Corrected Hedges' g (95% CI)	-0.344 (-0.685, -0.002)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Table 2.0501: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Disease-Related Fatigue
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	115 (88.5%)	47 (72.3%)	162 (83.1%)
Mean (SD)	-24.75 (33.73)	-14.10 (36.86)	-21.66 (34.89)
Median	-21.94	-12.72	-19.36
Q1, Q3	-51.39, -0.71	-42.31, 14.43	-50.00, 2.18
Min, Max	-100.0, 102.2	-100.0, 68.5	-100.0, 102.2
Return Rate (%)	88%	72%	
Number of Subjects in Risk	123	53	
Return Rate in Risk (%)	93%	89%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Table 2.0501: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Disease-Related Fatigue
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 16			
n (%)	100 (76.9%)	40 (61.5%)	140 (71.8%)
Mean (SD)	4.31 (2.34)	4.68 (2.31)	4.41 (2.33)
Median	4.25	4.17	4.25
Q1, Q3	2.64, 5.57	2.93, 6.89	2.71, 5.96
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 10.0
Change from Baseline			
n (%)	100 (76.9%)	40 (61.5%)	140 (71.8%)
Mean (SD)	-1.79 (2.26)	-0.62 (1.91)	-1.46 (2.22)
Median	-1.25	-0.26	-1.07
Q1, Q3	-3.11, -0.38	-1.87, 0.67	-2.66, 0.18
Min, Max	-8.5, 2.2	-5.7, 3.0	-8.5, 3.0
Least Squares Mean (SE) [1]	-1.53 (0.20)	-0.80 (0.29)	
95% CI [1]	-1.92, -1.14	-1.37, -0.23	
Least Squares Mean Difference (SE) [1]	-0.74 (0.35)		
95% CI [1]	-1.42, -0.05		
p-value [2]	0.035		
Corrected Hedges' g (95% CI)	-0.379 (-0.748, -0.009)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t_tss_chg_rt24_gba.sas V.03.05 Output file: t-c-drf-g.pdf 13SEP2023: 8:35

GSK Oncology

Study SRA-MMB-301

Table 2.0501: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Disease-Related Fatigue

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	100 (76.9%)	40 (61.5%)	140 (71.8%)
Mean (SD)	-26.49 (35.93)	-7.48 (41.94)	-21.06 (38.56)
Median	-23.48	-3.64	-18.95
Q1, Q3	-50.88, -6.39	-38.85, 20.18	-47.97, 2.46
Min, Max	-100.0, 103.3	-100.0, 132.1	-100.0, 132.1
Return Rate (%)	77%	62%	
Number of Subjects in Risk	113	48	
Return Rate in Risk (%)	88%	83%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.0501: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Disease-Related Fatigue
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 20			
n (%)	100 (76.9%)	36 (55.4%)	136 (69.7%)
Mean (SD)	4.47 (2.30)	4.36 (2.26)	4.44 (2.28)
Median	4.18	4.08	4.13
Q1, Q3	2.88, 5.84	2.91, 6.40	2.88, 5.93
Min, Max	0.7, 10.0	0.0, 10.0	0.0, 10.0
Change from Baseline			
n (%)	100 (76.9%)	36 (55.4%)	136 (69.7%)
Mean (SD)	-1.66 (2.21)	-0.84 (2.24)	-1.44 (2.24)
Median	-1.09	-0.60	-0.95
Q1, Q3	-2.74, -0.05	-2.63, 1.10	-2.72, 0.10
Min, Max	-8.1, 1.9	-5.8, 3.0	-8.1, 3.0
Least Squares Mean (SE) [1]	-1.51 (0.20)	-0.88 (0.30)	
95% CI [1]	-1.90, -1.11	-1.48, -0.29	
Least Squares Mean Difference (SE) [1]	-0.62 (0.36)		
95% CI [1]	-1.33, 0.08		
p-value [2]	0.083		
Corrected Hedges' g (95% CI)	-0.317 (-0.700, 0.066)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
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GSK Oncology

Study SRA-MMB-301

Table 2.0501: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Disease-Related Fatigue

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	100 (76.9%)	36 (55.4%)	136 (69.7%)
Mean (SD)	-23.61 (34.26)	-8.47 (50.34)	-19.60 (39.53)
Median	-22.08	-12.45	-19.28
Q1, Q3	-48.08, -0.94	-42.19, 20.78	-47.08, 1.87
Min, Max	-88.4, 70.5	-99.2, 173.1	-99.2, 173.1
Return Rate (%)	77%	55%	
Number of Subjects in Risk	106	42	
Return Rate in Risk (%)	94%	86%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.0501: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Disease-Related Fatigue

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 24			
n (%)	92 (70.8%)	37 (56.9%)	129 (66.2%)
Mean (SD)	4.39 (2.35)	4.52 (2.40)	4.43 (2.36)
Median	3.98	4.38	4.04
Q1, Q3	2.96, 6.06	3.04, 6.60	2.96, 6.11
Min, Max	0.2, 10.0	0.0, 10.0	0.0, 10.0
Change from Baseline			
n (%)	92 (70.8%)	37 (56.9%)	129 (66.2%)
Mean (SD)	-1.79 (2.20)	-0.81 (2.36)	-1.51 (2.28)
Median	-1.21	-0.40	-0.96
Q1, Q3	-3.11, -0.26	-2.40, 0.50	-2.86, 0.00
Min, Max	-8.4, 1.9	-5.9, 4.0	-8.4, 4.0
Least Squares Mean (SE) [1]	-1.53 (0.20)	-0.82 (0.31)	
95% CI [1]	-1.93, -1.13	-1.42, -0.22	
Least Squares Mean Difference (SE) [1]	-0.71 (0.36)		
95% CI [1]	-1.42, 0.00		
p-value [2]	0.051		
Corrected Hedges' g (95% CI)	-0.368 (-0.752, 0.017)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
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Study SRA-MMB-301

Table 2.0501: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Disease-Related Fatigue

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	92 (70.8%)	37 (56.9%)	129 (66.2%)
Mean (SD)	-26.13 (32.99)	-11.58 (44.01)	-21.95 (36.90)
Median	-20.48	-14.37	-18.38
Q1, Q3	-47.35, -3.35	-33.33, 17.50	-45.71, 0.00
Min, Max	-96.6, 63.3	-100.0, 96.6	-100.0, 96.6
Return Rate (%)	71%	57%	
Number of Subjects in Risk	99	39	
Return Rate in Risk (%)	93%	95%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

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Study SRA-MMB-301

Table 2.0506: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Fullness

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Fullness Item Score			
Baseline			
n (%)	130 (100%)	65 (100%)	195 (100%)
Mean (SD)	4.60 (2.54)	4.19 (2.24)	4.46 (2.45)
Median	4.86	4.33	4.57
Q1, Q3	2.50, 6.43	2.33, 5.86	2.43, 6.33
Min, Max	0.0, 9.7	0.0, 9.0	0.0, 9.7
Return Rate (%)	100%	100%	
Number of Subjects in Risk	130	65	
Return Rate in Risk (%)	100%	100%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

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Study SRA-MMB-301

Table 2.0506: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Fullness

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 4			
n (%)	121 (93.1%)	56 (86.2%)	177 (90.8%)
Mean (SD)	3.79 (2.34)	4.03 (2.23)	3.87 (2.30)
Median	3.57	4.24	3.79
Q1, Q3	2.18, 5.18	2.27, 5.23	2.22, 5.18
Min, Max	0.0, 8.9	0.0, 9.2	0.0, 9.2
Change from Baseline			
n (%)	121 (93.1%)	56 (86.2%)	177 (90.8%)
Mean (SD)	-0.75 (1.68)	-0.14 (1.20)	-0.56 (1.57)
Median	-0.46	0.00	-0.36
Q1, Q3	-1.54, 0.25	-0.74, 0.59	-1.25, 0.39
Min, Max	-5.6, 4.5	-3.4, 2.7	-5.6, 4.5
Least Squares Mean (SE) [1]	-0.67 (0.15)	-0.08 (0.21)	
95% CI [1]	-0.96, -0.38	-0.50, 0.33	
Least Squares Mean Difference (SE) [1]	-0.59 (0.25)		
95% CI [1]	-1.08, -0.10		
p-value [2]	0.018		
Corrected Hedges' g (95% CI)	-0.366 (-0.685, -0.047)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.0506: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Fullness

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	117 (90.0%)	55 (84.6%)	172 (88.2%)
Mean (SD)	-7.94 (79.89)	0.21 (39.16)	-5.33 (69.48)
Median	-12.96	0.00	-10.07
Q1, Q3	-43.91, 8.33	-20.19, 19.78	-37.55, 11.89
Min, Max	-100.0, 677.8	-92.9, 118.8	-100.0, 677.8
Return Rate (%)	93%	86%	
Number of Subjects in Risk	130	65	
Return Rate in Risk (%)	93%	86%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Study SRA-MMB-301

Table 2.0506: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Fullness

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 8			
n (%)	119 (91.5%)	54 (83.1%)	173 (88.7%)
Mean (SD)	3.32 (2.41)	3.68 (2.28)	3.43 (2.37)
Median	2.89	3.34	3.05
Q1, Q3	1.46, 5.00	2.11, 5.21	1.65, 5.13
Min, Max	0.0, 9.0	0.0, 9.3	0.0, 9.3
Change from Baseline			
n (%)	119 (91.5%)	54 (83.1%)	173 (88.7%)
Mean (SD)	-1.37 (2.21)	-0.56 (1.53)	-1.12 (2.06)
Median	-1.18	-0.15	-0.71
Q1, Q3	-2.57, 0.11	-1.41, 0.38	-2.33, 0.18
Min, Max	-9.3, 2.6	-4.0, 2.0	-9.3, 2.6
Least Squares Mean (SE) [1]	-1.18 (0.19)	-0.38 (0.27)	
95% CI [1]	-1.55, -0.81	-0.91, 0.15	
Least Squares Mean Difference (SE) [1]	-0.80 (0.32)		
95% CI [1]	-1.43, -0.17		
p-value [2]	0.013		
Corrected Hedges' g (95% CI)	-0.396 (-0.720, -0.071)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

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Study SRA-MMB-301

Table 2.0506: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Fullness

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	116 (89.2%)	53 (81.5%)	169 (86.7%)
Mean (SD)	-27.25 (49.28)	-9.80 (38.18)	-21.78 (46.69)
Median	-29.14	-3.98	-21.88
Q1, Q3	-65.49, 0.50	-34.65, 14.77	-52.78, 4.18
Min, Max	-100.0, 215.0	-100.0, 76.4	-100.0, 215.0
Return Rate (%)	92%	83%	
Number of Subjects in Risk	129	63	
Return Rate in Risk (%)	92%	86%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.0506: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Fullness

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 12			
n (%)	115 (88.5%)	47 (72.3%)	162 (83.1%)
Mean (SD)	3.11 (2.29)	3.27 (2.16)	3.15 (2.25)
Median	2.70	3.36	2.76
Q1, Q3	1.12, 4.67	1.71, 4.77	1.25, 4.68
Min, Max	0.0, 9.0	0.0, 10.0	0.0, 10.0
Change from Baseline			
n (%)	115 (88.5%)	47 (72.3%)	162 (83.1%)
Mean (SD)	-1.61 (2.38)	-0.74 (1.70)	-1.36 (2.23)
Median	-1.46	-0.29	-0.91
Q1, Q3	-2.93, 0.03	-1.33, 0.14	-2.57, 0.07
Min, Max	-8.5, 3.0	-5.3, 2.9	-8.5, 3.0
Least Squares Mean (SE) [1]	-1.36 (0.20)	-0.55 (0.29)	
95% CI [1]	-1.75, -0.96	-1.12, 0.02	
Least Squares Mean Difference (SE) [1]	-0.80 (0.34)		
95% CI [1]	-1.48, -0.12		
p-value [2]	0.021		
Corrected Hedges' g (95% CI)	-0.382 (-0.724, -0.041)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Table 2.0506: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Fullness

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	112 (86.2%)	46 (70.8%)	158 (81.0%)
Mean (SD)	-28.40 (55.66)	-14.90 (37.18)	-24.47 (51.23)
Median	-37.16	-13.24	-25.15
Q1, Q3	-66.08, 0.33	-27.72, 5.98	-62.50, 0.83
Min, Max	-100.0, 250.0	-100.0, 75.0	-100.0, 250.0
Return Rate (%)	88%	72%	
Number of Subjects in Risk	123	53	
Return Rate in Risk (%)	93%	89%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Study SRA-MMB-301

Table 2.0506: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Fullness

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 16			
n (%)	100 (76.9%)	40 (61.5%)	140 (71.8%)
Mean (SD)	2.78 (2.15)	3.44 (2.28)	2.97 (2.20)
Median	2.33	3.02	2.55
Q1, Q3	1.02, 4.23	1.98, 5.07	1.14, 4.48
Min, Max	0.0, 9.1	0.0, 10.0	0.0, 10.0
Change from Baseline			
n (%)	100 (76.9%)	40 (61.5%)	140 (71.8%)
Mean (SD)	-1.92 (2.48)	-0.69 (2.09)	-1.57 (2.43)
Median	-1.75	-0.25	-1.34
Q1, Q3	-3.54, -0.12	-1.86, 0.39	-2.86, 0.01
Min, Max	-8.2, 2.5	-6.0, 4.8	-8.2, 4.8
Least Squares Mean (SE) [1]	-1.49 (0.21)	-0.51 (0.31)	
95% CI [1]	-1.91, -1.08	-1.12, 0.10	
Least Squares Mean Difference (SE) [1]	-0.98 (0.37)		
95% CI [1]	-1.71, -0.25		
p-value [2]	0.009		
Corrected Hedges' g (95% CI)	-0.472 (-0.843, -0.101)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.0506: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Fullness

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	96 (73.8%)	39 (60.0%)	135 (69.2%)
Mean (SD)	-33.36 (60.31)	-10.11 (50.14)	-26.65 (58.34)
Median	-44.45	-12.50	-32.35
Q1, Q3	-71.75, -11.88	-46.15, 13.17	-66.67, 0.00
Min, Max	-100.0, 273.3	-100.0, 198.9	-100.0, 273.3
Return Rate (%)	77%	62%	
Number of Subjects in Risk	113	48	
Return Rate in Risk (%)	88%	83%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t_tss_chg_rt24_gba.sas V.03.05 Output file: t-c-full-g.pdf 13SEP2023: 8:35

Table 2.0506: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Fullness

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 20			
n (%)	100 (76.9%)	36 (55.4%)	136 (69.7%)
Mean (SD)	2.76 (2.12)	3.20 (2.19)	2.88 (2.14)
Median	2.18	3.00	2.44
Q1, Q3	1.04, 4.11	1.84, 4.51	1.15, 4.24
Min, Max	0.0, 9.0	0.0, 10.0	0.0, 10.0
Change from Baseline			
n (%)	100 (76.9%)	36 (55.4%)	136 (69.7%)
Mean (SD)	-1.92 (2.49)	-1.17 (2.11)	-1.72 (2.41)
Median	-1.58	-0.43	-1.47
Q1, Q3	-3.33, -0.09	-2.60, 0.34	-3.27, 0.07
Min, Max	-8.6, 2.6	-6.1, 2.9	-8.6, 2.9
Least Squares Mean (SE) [1]	-1.57 (0.22)	-0.58 (0.33)	
95% CI [1]	-2.01, -1.13	-1.23, 0.07	
Least Squares Mean Difference (SE) [1]	-0.99 (0.39)		
95% CI [1]	-1.76, -0.22		
p-value [2]	0.012		
Corrected Hedges' g (95% CI)	-0.457 (-0.842, -0.072)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t_tss_chg_rt24_gba.sas V.03.05 Output file: t-c-full-g.pdf 13SEP2023: 8:35

Table 2.0506: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Fullness

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	97 (74.6%)	36 (55.4%)	133 (68.2%)
Mean (SD)	-33.02 (59.67)	-21.25 (45.17)	-29.84 (56.19)
Median	-43.00	-19.93	-37.75
Q1, Q3	-72.44, -5.00	-58.37, 8.27	-67.69, 0.00
Min, Max	-100.0, 298.2	-100.0, 71.7	-100.0, 298.2
Return Rate (%)	77%	55%	
Number of Subjects in Risk	106	42	
Return Rate in Risk (%)	94%	86%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t_tss_chg_rt24_gba.sas V.03.05 Output file: t-c-full-g.pdf 13SEP2023: 8:35

Table 2.0506: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Fullness

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 24			
n (%)	92 (70.8%)	37 (56.9%)	129 (66.2%)
Mean (SD)	2.84 (2.20)	3.05 (2.26)	2.90 (2.21)
Median	2.15	3.00	2.39
Q1, Q3	1.14, 4.67	1.74, 4.15	1.33, 4.67
Min, Max	0.0, 9.0	0.0, 10.0	0.0, 10.0
Change from Baseline			
n (%)	92 (70.8%)	37 (56.9%)	129 (66.2%)
Mean (SD)	-1.93 (2.60)	-1.27 (2.05)	-1.74 (2.46)
Median	-1.64	-0.69	-1.39
Q1, Q3	-3.38, -0.08	-2.57, 0.00	-3.02, -0.01
Min, Max	-8.6, 3.1	-6.1, 2.9	-8.6, 3.1
Least Squares Mean (SE) [1]	-1.51 (0.23)	-0.73 (0.34)	
95% CI [1]	-1.96, -1.07	-1.40, -0.06	
Least Squares Mean Difference (SE) [1]	-0.78 (0.40)		
95% CI [1]	-1.58, 0.01		
p-value [2]	0.053		
Corrected Hedges' g (95% CI)	-0.364 (-0.748, 0.021)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
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GSK Oncology

Study SRA-MMB-301

Table 2.0506: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Fullness

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	89 (68.5%)	36 (55.4%)	125 (64.1%)
Mean (SD)	-31.27 (62.74)	-27.28 (44.63)	-30.12 (57.95)
Median	-40.55	-25.06	-38.46
Q1, Q3	-70.63, -6.67	-65.91, -0.50	-68.13, -6.08
Min, Max	-100.0, 281.4	-100.0, 88.5	-100.0, 281.4
Return Rate (%)	71%	57%	
Number of Subjects in Risk	99	39	
Return Rate in Risk (%)	93%	95%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

GSK Oncology

Study SRA-MMB-301

Table 2.0503: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Itching

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Itching Item Score			
Baseline			
n (%)	130 (100%)	65 (100%)	195 (100%)
Mean (SD)	2.77 (2.74)	3.03 (2.67)	2.86 (2.71)
Median	1.86	2.71	2.29
Q1, Q3	0.43, 4.86	0.29, 5.14	0.43, 5.00
Min, Max	0.0, 10.0	0.0, 9.1	0.0, 10.0
Return Rate (%)	100%	100%	
Number of Subjects in Risk	130	65	
Return Rate in Risk (%)	100%	100%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.0503: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Itching

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 4			
n (%)	121 (93.1%)	56 (86.2%)	177 (90.8%)
Mean (SD)	1.94 (2.02)	2.31 (2.14)	2.06 (2.06)
Median	1.25	1.93	1.44
Q1, Q3	0.18, 3.08	0.34, 3.75	0.22, 3.26
Min, Max	0.0, 9.3	0.0, 9.7	0.0, 9.7
Change from Baseline			
n (%)	121 (93.1%)	56 (86.2%)	177 (90.8%)
Mean (SD)	-0.77 (1.52)	-0.55 (1.56)	-0.70 (1.53)
Median	-0.34	-0.14	-0.21
Q1, Q3	-1.43, 0.11	-1.28, 0.20	-1.43, 0.14
Min, Max	-6.7, 1.9	-5.7, 3.4	-6.7, 3.4
Least Squares Mean (SE) [1]	-0.78 (0.14)	-0.58 (0.20)	
95% CI [1]	-1.06, -0.50	-0.98, -0.18	
Least Squares Mean Difference (SE) [1]	-0.21 (0.24)		
95% CI [1]	-0.68, 0.27		
p-value [2]	0.39		
Corrected Hedges' g (95% CI)	-0.131 (-0.448, 0.186)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
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Table 2.0503: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Itching

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	98 (75.4%)	43 (66.2%)	141 (72.3%)
Mean (SD)	-4.57 (120.58)	16.29 (150.27)	1.79 (130.15)
Median	-32.53	-23.22	-31.47
Q1, Q3	-50.71, 12.20	-47.97, 15.00	-49.23, 12.20
Min, Max	-100.0, 735.7	-100.0, 783.3	-100.0, 783.3
Return Rate (%)	93%	86%	
Number of Subjects in Risk	130	65	
Return Rate in Risk (%)	93%	86%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Table 2.0503: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Itching

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 8			
n (%)	119 (91.5%)	54 (83.1%)	173 (88.7%)
Mean (SD)	1.60 (1.71)	2.28 (2.00)	1.81 (1.83)
Median	1.20	1.84	1.29
Q1, Q3	0.00, 2.75	0.62, 3.59	0.04, 2.96
Min, Max	0.0, 7.5	0.0, 9.4	0.0, 9.4
Change from Baseline			
n (%)	119 (91.5%)	54 (83.1%)	173 (88.7%)
Mean (SD)	-1.05 (2.19)	-0.83 (2.29)	-0.98 (2.22)
Median	-0.43	-0.07	-0.39
Q1, Q3	-1.77, 0.04	-2.17, 0.50	-1.95, 0.16
Min, Max	-8.6, 2.9	-8.6, 5.0	-8.6, 5.0
Least Squares Mean (SE) [1]	-1.08 (0.20)	-0.83 (0.28)	
95% CI [1]	-1.46, -0.69	-1.39, -0.27	
Least Squares Mean Difference (SE) [1]	-0.24 (0.34)		
95% CI [1]	-0.91, 0.42		
p-value [2]	0.47		
Corrected Hedges' g (95% CI)	-0.114 (-0.436, 0.208)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
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Table 2.0503: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Itching

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	96 (73.8%)	42 (64.6%)	138 (70.8%)
Mean (SD)	-8.17 (138.13)	46.63 (313.22)	8.51 (207.92)
Median	-39.66	-32.26	-35.03
Q1, Q3	-80.21, 9.15	-67.59, 16.67	-77.14, 10.38
Min, Max	-100.0, 887.5	-100.0, 1744.2	-100.0, 1744.2
Return Rate (%)	92%	83%	
Number of Subjects in Risk	129	63	
Return Rate in Risk (%)	92%	86%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.0503: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Itching

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 12			
n (%)	115 (88.5%)	47 (72.3%)	162 (83.1%)
Mean (SD)	1.65 (1.81)	2.08 (1.66)	1.77 (1.77)
Median	1.16	1.75	1.32
Q1, Q3	0.00, 2.81	0.89, 3.57	0.04, 2.92
Min, Max	0.0, 8.3	0.0, 5.4	0.0, 8.3
Change from Baseline			
n (%)	115 (88.5%)	47 (72.3%)	162 (83.1%)
Mean (SD)	-1.08 (2.41)	-0.83 (2.13)	-1.01 (2.33)
Median	-0.62	-0.32	-0.59
Q1, Q3	-2.21, 0.06	-2.63, 0.25	-2.32, 0.17
Min, Max	-9.0, 3.6	-5.3, 4.5	-9.0, 4.5
Least Squares Mean (SE) [1]	-1.06 (0.21)	-0.90 (0.31)	
95% CI [1]	-1.47, -0.64	-1.51, -0.29	
Least Squares Mean Difference (SE) [1]	-0.16 (0.37)		
95% CI [1]	-0.88, 0.57		
p-value [2]	0.67		
Corrected Hedges' g (95% CI)	-0.070 (-0.409, 0.269)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
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Table 2.0503: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Itching

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	95 (73.1%)	37 (56.9%)	132 (67.7%)
Mean (SD)	-1.11 (173.30)	34.42 (282.31)	8.85 (209.07)
Median	-42.76	-26.56	-40.46
Q1, Q3	-92.70, 16.67	-65.66, 6.09	-79.04, 11.34
Min, Max	-100.0, 1262.5	-97.6, 1580.0	-100.0, 1580.0
Return Rate (%)	88%	72%	
Number of Subjects in Risk	123	53	
Return Rate in Risk (%)	93%	89%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t_tss_chg_rt24_gba.sas V.03.05 Output file: t-c-itch-g.pdf 13SEP2023: 8:35

Table 2.0503: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Itching

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 16			
n (%)	100 (76.9%)	40 (61.5%)	140 (71.8%)
Mean (SD)	1.76 (1.99)	1.99 (1.85)	1.83 (1.95)
Median	1.08	1.40	1.29
Q1, Q3	0.00, 2.77	0.42, 3.18	0.04, 2.92
Min, Max	0.0, 8.6	0.0, 7.9	0.0, 8.6
Change from Baseline			
n (%)	100 (76.9%)	40 (61.5%)	140 (71.8%)
Mean (SD)	-1.03 (2.44)	-0.65 (2.52)	-0.92 (2.46)
Median	-0.43	-0.11	-0.32
Q1, Q3	-1.79, 0.09	-2.67, 0.47	-2.23, 0.18
Min, Max	-9.0, 5.1	-5.6, 7.6	-9.0, 7.6
Least Squares Mean (SE) [1]	-1.03 (0.23)	-0.94 (0.34)	
95% CI [1]	-1.48, -0.58	-1.61, -0.27	
Least Squares Mean Difference (SE) [1]	-0.09 (0.40)		
95% CI [1]	-0.88, 0.71		
p-value [2]	0.83		
Corrected Hedges' g (95% CI)	-0.038 (-0.405, 0.328)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
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Table 2.0503: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Itching

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	84 (64.6%)	31 (47.7%)	115 (59.0%)
Mean (SD)	13.63 (221.86)	67.33 (489.58)	28.10 (315.41)
Median	-41.80	-42.86	-41.89
Q1, Q3	-90.52, 13.75	-74.36, 6.94	-87.74, 10.83
Min, Max	-100.0, 1400.0	-98.7, 2673.1	-100.0, 2673.1
Return Rate (%)	77%	62%	
Number of Subjects in Risk	113	48	
Return Rate in Risk (%)	88%	83%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t_tss_chg_rt24_gba.sas V.03.05 Output file: t-c-itch-g.pdf 13SEP2023: 8:35

Table 2.0503: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Itching

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 20			
n (%)	100 (76.9%)	36 (55.4%)	136 (69.7%)
Mean (SD)	1.60 (1.85)	2.04 (1.99)	1.71 (1.89)
Median	1.04	1.40	1.04
Q1, Q3	0.00, 2.65	0.36, 3.08	0.00, 2.75
Min, Max	0.0, 9.2	0.0, 7.6	0.0, 9.2
Change from Baseline			
n (%)	100 (76.9%)	36 (55.4%)	136 (69.7%)
Mean (SD)	-1.11 (2.48)	-0.64 (2.46)	-0.98 (2.47)
Median	-0.34	-0.30	-0.34
Q1, Q3	-1.97, 0.12	-2.58, 0.19	-2.23, 0.14
Min, Max	-9.0, 4.8	-5.8, 7.3	-9.0, 7.3
Least Squares Mean (SE) [1]	-1.12 (0.23)	-0.79 (0.34)	
95% CI [1]	-1.58, -0.67	-1.46, -0.12	
Least Squares Mean Difference (SE) [1]	-0.33 (0.41)		
95% CI [1]	-1.13, 0.47		
p-value [2]	0.41		
Corrected Hedges' g (95% CI)	-0.148 (-0.530, 0.233)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t_tss_chg_rt24_gba.sas V.03.05 Output file: t-c-itch-g.pdf 13SEP2023: 8:35

Table 2.0503: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Itching

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	84 (64.6%)	29 (44.6%)	113 (57.9%)
Mean (SD)	9.47 (221.14)	79.99 (492.40)	27.57 (312.75)
Median	-41.74	-48.15	-43.75
Q1, Q3	-90.46, 10.27	-67.57, 5.73	-85.00, 8.60
Min, Max	-100.0, 1611.1	-100.0, 2568.8	-100.0, 2568.8
Return Rate (%)	77%	55%	
Number of Subjects in Risk	106	42	
Return Rate in Risk (%)	94%	86%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t_tss_chg_rt24_gba.sas V.03.05 Output file: t-c-itch-g.pdf 13SEP2023: 8:35

Table 2.0503: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Itching

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 24			
n (%)	92 (70.8%)	37 (56.9%)	129 (66.2%)
Mean (SD)	1.56 (1.85)	2.10 (1.95)	1.71 (1.89)
Median	1.07	1.88	1.14
Q1, Q3	0.00, 2.25	0.19, 3.19	0.00, 2.61
Min, Max	0.0, 9.3	0.0, 7.6	0.0, 9.3
Change from Baseline			
n (%)	92 (70.8%)	37 (56.9%)	129 (66.2%)
Mean (SD)	-1.31 (2.49)	-0.73 (2.58)	-1.15 (2.52)
Median	-0.62	-0.88	-0.67
Q1, Q3	-2.48, 0.00	-2.23, 0.26	-2.36, 0.05
Min, Max	-9.0, 5.0	-6.6, 7.3	-9.0, 7.3
Least Squares Mean (SE) [1]	-1.16 (0.24)	-0.85 (0.35)	
95% CI [1]	-1.63, -0.69	-1.54, -0.15	
Least Squares Mean Difference (SE) [1]	-0.31 (0.42)		
95% CI [1]	-1.14, 0.51		
p-value [2]	0.45		
Corrected Hedges' g (95% CI)	-0.140 (-0.522, 0.242)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t_tss_chg_rt24_gba.sas V.03.05 Output file: t-c-itch-g.pdf 13SEP2023: 8:35

Table 2.0503: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Itching

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	78 (60.0%)	31 (47.7%)	109 (55.9%)
Mean (SD)	-1.15 (230.79)	67.38 (474.71)	18.34 (318.65)
Median	-51.66	-40.03	-44.59
Q1, Q3	-87.50, 1.82	-79.73, 11.20	-86.36, 2.08
Min, Max	-100.0, 1753.7	-100.0, 2562.5	-100.0, 2562.5
Return Rate (%)	71%	57%	
Number of Subjects in Risk	99	39	
Return Rate in Risk (%)	93%	95%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
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Table 2.0502: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Night Sweats

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Night Sweats Item Score			
Baseline			
n (%)	130 (100%)	65 (100%)	195 (100%)
Mean (SD)	3.43 (2.85)	3.05 (2.44)	3.30 (2.72)
Median	3.00	2.57	2.83
Q1, Q3	0.71, 5.57	0.86, 5.14	0.86, 5.43
Min, Max	0.0, 10.0	0.0, 7.7	0.0, 10.0
Return Rate (%)	100%	100%	
Number of Subjects in Risk	130	65	
Return Rate in Risk (%)	100%	100%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.0502: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Night Sweats

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 4			
n (%)	121 (93.1%)	56 (86.2%)	177 (90.8%)
Mean (SD)	2.19 (2.26)	2.71 (2.18)	2.36 (2.24)
Median	1.86	2.38	1.88
Q1, Q3	0.31, 3.18	0.93, 3.95	0.36, 3.54
Min, Max	0.0, 9.7	0.0, 9.1	0.0, 9.7
Change from Baseline			
n (%)	121 (93.1%)	56 (86.2%)	177 (90.8%)
Mean (SD)	-1.24 (1.65)	-0.22 (1.21)	-0.91 (1.59)
Median	-0.82	-0.13	-0.45
Q1, Q3	-2.39, -0.01	-0.91, 0.43	-1.85, 0.00
Min, Max	-6.6, 2.6	-3.8, 2.3	-6.6, 2.6
Least Squares Mean (SE) [1]	-1.16 (0.14)	-0.16 (0.20)	
95% CI [1]	-1.43, -0.89	-0.55, 0.23	
Least Squares Mean Difference (SE) [1]	-1.00 (0.23)		
95% CI [1]	-1.46, -0.54		
p-value [2]	<0.001		
Corrected Hedges' g (95% CI)	-0.662 (-0.987, -0.338)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t_tss_chg_rt24_gba.sas V.03.05 Output file: t-c-ns-g.pdf 13SEP2023: 8:35

Table 2.0502: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Night Sweats

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	103 (79.2%)	49 (75.4%)	152 (77.9%)
Mean (SD)	-40.54 (38.94)	14.20 (92.25)	-22.89 (66.24)
Median	-39.71	-6.94	-28.10
Q1, Q3	-68.59, -14.29	-28.07, 21.90	-62.96, -3.66
Min, Max	-100.0, 125.0	-96.9, 381.3	-100.0, 381.3
Return Rate (%)	93%	86%	
Number of Subjects in Risk	130	65	
Return Rate in Risk (%)	93%	86%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Table 2.0502: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Night Sweats

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 8			
n (%)	119 (91.5%)	54 (83.1%)	173 (88.7%)
Mean (SD)	1.81 (2.04)	2.52 (2.17)	2.03 (2.10)
Median	1.21	2.00	1.48
Q1, Q3	0.08, 2.57	0.61, 3.89	0.23, 3.29
Min, Max	0.0, 9.6	0.0, 9.0	0.0, 9.6
Change from Baseline			
n (%)	119 (91.5%)	54 (83.1%)	173 (88.7%)
Mean (SD)	-1.67 (2.17)	-0.53 (1.78)	-1.31 (2.12)
Median	-0.93	-0.01	-0.63
Q1, Q3	-3.00, 0.00	-1.32, 0.38	-2.65, 0.00
Min, Max	-9.1, 2.5	-6.1, 3.7	-9.1, 3.7
Least Squares Mean (SE) [1]	-1.52 (0.18)	-0.48 (0.26)	
95% CI [1]	-1.87, -1.17	-0.98, 0.03	
Least Squares Mean Difference (SE) [1]	-1.04 (0.30)		
95% CI [1]	-1.64, -0.44		
p-value [2]	<0.001		
Corrected Hedges' g (95% CI)	-0.542 (-0.868, -0.215)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Table 2.0502: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Night Sweats

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	101 (77.7%)	47 (72.3%)	148 (75.9%)
Mean (SD)	-39.97 (84.59)	5.12 (105.75)	-25.65 (93.87)
Median	-58.36	-10.71	-43.94
Q1, Q3	-83.95, -18.37	-40.24, 14.94	-73.10, -3.31
Min, Max	-100.0, 656.0	-100.0, 560.0	-100.0, 656.0
Return Rate (%)	92%	83%	
Number of Subjects in Risk	129	63	
Return Rate in Risk (%)	92%	86%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Table 2.0502: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Night Sweats

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 12			
n (%)	115 (88.5%)	47 (72.3%)	162 (83.1%)
Mean (SD)	1.89 (2.02)	2.35 (2.15)	2.02 (2.06)
Median	1.12	1.70	1.53
Q1, Q3	0.00, 3.12	0.52, 3.93	0.11, 3.29
Min, Max	0.0, 9.1	0.0, 8.7	0.0, 9.1
Change from Baseline			
n (%)	115 (88.5%)	47 (72.3%)	162 (83.1%)
Mean (SD)	-1.58 (2.26)	-0.49 (2.00)	-1.26 (2.23)
Median	-0.86	-0.07	-0.64
Q1, Q3	-2.85, 0.00	-1.39, 0.36	-2.49, 0.00
Min, Max	-9.1, 2.9	-5.6, 6.1	-9.1, 6.1
Least Squares Mean (SE) [1]	-1.47 (0.19)	-0.45 (0.28)	
95% CI [1]	-1.85, -1.10	-1.00, 0.10	
Least Squares Mean Difference (SE) [1]	-1.02 (0.33)		
95% CI [1]	-1.68, -0.37		
p-value [2]	0.002		
Corrected Hedges' g (95% CI)	-0.510 (-0.854, -0.166)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Table 2.0502: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Night Sweats

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	98 (75.4%)	40 (61.5%)	138 (70.8%)
Mean (SD)	-35.07 (91.86)	11.49 (125.43)	-21.58 (104.42)
Median	-56.02	-17.66	-40.07
Q1, Q3	-85.53, -12.25	-49.33, 27.34	-76.47, -3.57
Min, Max	-100.0, 684.0	-97.7, 614.3	-100.0, 684.0
Return Rate (%)	88%	72%	
Number of Subjects in Risk	123	53	
Return Rate in Risk (%)	93%	89%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Table 2.0502: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Night Sweats

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 16			
n (%)	100 (76.9%)	40 (61.5%)	140 (71.8%)
Mean (SD)	1.79 (2.01)	2.41 (1.98)	1.97 (2.01)
Median	1.12	2.00	1.47
Q1, Q3	0.11, 2.90	0.63, 3.66	0.14, 3.02
Min, Max	0.0, 9.0	0.0, 7.4	0.0, 9.0
Change from Baseline			
n (%)	100 (76.9%)	40 (61.5%)	140 (71.8%)
Mean (SD)	-1.81 (2.30)	-0.32 (1.88)	-1.39 (2.28)
Median	-1.23	-0.23	-0.83
Q1, Q3	-3.08, 0.00	-1.18, 0.34	-2.71, 0.00
Min, Max	-9.0, 3.5	-4.4, 4.8	-9.0, 4.8
Least Squares Mean (SE) [1]	-1.51 (0.19)	-0.44 (0.28)	
95% CI [1]	-1.89, -1.13	-1.00, 0.12	
Least Squares Mean Difference (SE) [1]	-1.07 (0.34)		
95% CI [1]	-1.73, -0.41		
p-value [2]	0.002		
Corrected Hedges' g (95% CI)	-0.564 (-0.937, -0.191)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Table 2.0502: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Night Sweats

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	88 (67.7%)	33 (50.8%)	121 (62.1%)
Mean (SD)	-36.33 (111.80)	9.37 (98.55)	-23.87 (109.86)
Median	-59.73	-22.97	-47.22
Q1, Q3	-87.20, -22.29	-40.45, 8.47	-73.08, -13.89
Min, Max	-100.0, 862.5	-100.0, 300.0	-100.0, 862.5
Return Rate (%)	77%	62%	
Number of Subjects in Risk	113	48	
Return Rate in Risk (%)	88%	83%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
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GSK Oncology

Study SRA-MMB-301

Table 2.0502: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Night Sweats

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 20			
n (%)	100 (76.9%)	36 (55.4%)	136 (69.7%)
Mean (SD)	1.80 (2.11)	2.34 (2.15)	1.94 (2.13)
Median	1.00	1.79	1.22
Q1, Q3	0.04, 2.93	0.37, 3.66	0.09, 2.98
Min, Max	0.0, 9.0	0.0, 7.2	0.0, 9.0
Change from Baseline			
n (%)	100 (76.9%)	36 (55.4%)	136 (69.7%)
Mean (SD)	-1.71 (2.30)	-0.42 (1.99)	-1.37 (2.29)
Median	-1.02	-0.25	-0.78
Q1, Q3	-2.90, 0.00	-1.14, 0.69	-2.58, 0.00
Min, Max	-9.1, 2.8	-5.8, 4.6	-9.1, 4.6
Least Squares Mean (SE) [1]	-1.53 (0.20)	-0.47 (0.29)	
95% CI [1]	-1.91, -1.14	-1.05, 0.10	
Least Squares Mean Difference (SE) [1]	-1.05 (0.34)		
95% CI [1]	-1.73, -0.37		
p-value [2]	0.003		
Corrected Hedges' g (95% CI)	-0.551 (-0.937, -0.164)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.0502: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Night Sweats

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	86 (66.2%)	30 (46.2%)	116 (59.5%)
Mean (SD)	-38.55 (96.72)	-8.43 (87.56)	-30.76 (94.99)
Median	-60.28	-22.26	-49.79
Q1, Q3	-86.10, -18.33	-67.00, 26.32	-85.05, -7.89
Min, Max	-100.0, 703.7	-100.0, 293.6	-100.0, 703.7
Return Rate (%)	77%	55%	
Number of Subjects in Risk	106	42	
Return Rate in Risk (%)	94%	86%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
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Table 2.0502: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Night Sweats

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 24			
n (%)	92 (70.8%)	37 (56.9%)	129 (66.2%)
Mean (SD)	1.86 (2.20)	2.67 (2.42)	2.09 (2.28)
Median	1.05	1.96	1.29
Q1, Q3	0.04, 2.96	1.00, 3.89	0.04, 3.15
Min, Max	0.0, 9.0	0.0, 9.2	0.0, 9.2
Change from Baseline			
n (%)	92 (70.8%)	37 (56.9%)	129 (66.2%)
Mean (SD)	-1.86 (2.46)	-0.25 (2.24)	-1.40 (2.50)
Median	-1.39	-0.30	-0.79
Q1, Q3	-3.25, -0.01	-0.86, 0.50	-2.82, 0.00
Min, Max	-9.1, 3.5	-5.9, 4.9	-9.1, 4.9
Least Squares Mean (SE) [1]	-1.60 (0.21)	-0.33 (0.32)	
95% CI [1]	-2.01, -1.18	-0.95, 0.29	
Least Squares Mean Difference (SE) [1]	-1.27 (0.37)		
95% CI [1]	-2.00, -0.53		
p-value [2]	<0.001		
Corrected Hedges' g (95% CI)	-0.633 (-1.022, -0.243)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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GSK Oncology

Study SRA-MMB-301

Table 2.0502: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Night Sweats

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	80 (61.5%)	32 (49.2%)	112 (57.4%)
Mean (SD)	-36.55 (112.26)	-11.39 (83.96)	-29.37 (105.21)
Median	-69.25	-14.03	-56.68
Q1, Q3	-93.15, -15.73	-66.56, 15.75	-89.47, -10.03
Min, Max	-100.0, 725.0	-100.0, 313.6	-100.0, 725.0
Return Rate (%)	71%	57%	
Number of Subjects in Risk	99	39	
Return Rate in Risk (%)	93%	95%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

GSK Oncology

Study SRA-MMB-301

Table 2.0505: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Rib Pain

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Rib Pain Item Score			
Baseline			
n (%)	130 (100%)	65 (100%)	195 (100%)
Mean (SD)	3.31 (2.66)	2.81 (2.52)	3.14 (2.62)
Median	3.00	2.29	2.71
Q1, Q3	1.00, 5.14	0.71, 4.71	0.83, 4.86
Min, Max	0.0, 9.9	0.0, 8.6	0.0, 9.9
Return Rate (%)	100%	100%	
Number of Subjects in Risk	130	65	
Return Rate in Risk (%)	100%	100%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.0505: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Rib Pain

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 4			
n (%)	121 (93.1%)	56 (86.2%)	177 (90.8%)
Mean (SD)	2.43 (2.17)	2.36 (2.38)	2.41 (2.23)
Median	1.96	1.77	1.93
Q1, Q3	0.61, 3.50	0.05, 3.57	0.50, 3.54
Min, Max	0.0, 8.3	0.0, 8.4	0.0, 8.4
Change from Baseline			
n (%)	121 (93.1%)	56 (86.2%)	177 (90.8%)
Mean (SD)	-0.80 (1.70)	-0.38 (1.06)	-0.67 (1.53)
Median	-0.43	-0.08	-0.34
Q1, Q3	-1.72, 0.11	-1.03, 0.07	-1.51, 0.11
Min, Max	-6.4, 5.9	-2.7, 1.9	-6.4, 5.9
Least Squares Mean (SE) [1]	-0.75 (0.14)	-0.27 (0.20)	
95% CI [1]	-1.02, -0.47	-0.67, 0.12	
Least Squares Mean Difference (SE) [1]	-0.47 (0.23)		
95% CI [1]	-0.93, -0.01		
p-value [2]	0.044		
Corrected Hedges' g (95% CI)	-0.311 (-0.629, 0.008)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Table 2.0505: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Rib Pain

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	104 (80.0%)	46 (70.8%)	150 (76.9%)
Mean (SD)	-10.88 (93.17)	-20.47 (46.84)	-13.82 (81.75)
Median	-29.57	-17.07	-24.35
Q1, Q3	-56.35, 6.12	-47.73, 5.26	-54.55, 5.26
Min, Max	-100.0, 585.7	-100.0, 123.9	-100.0, 585.7
Return Rate (%)	93%	86%	
Number of Subjects in Risk	130	65	
Return Rate in Risk (%)	93%	86%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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GSK Oncology

Study SRA-MMB-301

Table 2.0505: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Rib Pain

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 8			
n (%)	119 (91.5%)	54 (83.1%)	173 (88.7%)
Mean (SD)	1.94 (2.21)	2.28 (2.21)	2.05 (2.21)
Median	1.21	1.73	1.54
Q1, Q3	0.12, 2.81	0.43, 3.46	0.19, 3.05
Min, Max	0.0, 8.6	0.0, 9.2	0.0, 9.2
Change from Baseline			
n (%)	119 (91.5%)	54 (83.1%)	173 (88.7%)
Mean (SD)	-1.39 (2.21)	-0.46 (1.46)	-1.10 (2.05)
Median	-0.93	-0.08	-0.56
Q1, Q3	-2.63, 0.12	-1.36, 0.29	-2.37, 0.19
Min, Max	-7.9, 4.3	-3.5, 3.5	-7.9, 4.3
Least Squares Mean (SE) [1]	-1.26 (0.18)	-0.38 (0.26)	
95% CI [1]	-1.62, -0.91	-0.89, 0.13	
Least Squares Mean Difference (SE) [1]	-0.88 (0.31)		
95% CI [1]	-1.49, -0.28		
p-value [2]	0.004		
Corrected Hedges' g (95% CI)	-0.455 (-0.780, -0.130)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.0505: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Rib Pain

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	103 (79.2%)	45 (69.2%)	148 (75.9%)
Mean (SD)	-26.18 (106.46)	16.48 (185.38)	-13.21 (136.16)
Median	-48.96	-9.26	-36.28
Q1, Q3	-86.42, 3.85	-38.24, 9.40	-78.48, 5.28
Min, Max	-100.0, 695.5	-100.0, 1150.0	-100.0, 1150.0
Return Rate (%)	92%	83%	
Number of Subjects in Risk	129	63	
Return Rate in Risk (%)	92%	86%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Table 2.0505: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Rib Pain

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 12			
n (%)	115 (88.5%)	47 (72.3%)	162 (83.1%)
Mean (SD)	1.98 (2.14)	2.09 (2.15)	2.01 (2.14)
Median	1.39	1.40	1.40
Q1, Q3	0.13, 3.11	0.07, 3.21	0.13, 3.11
Min, Max	0.0, 8.4	0.0, 7.5	0.0, 8.4
Change from Baseline			
n (%)	115 (88.5%)	47 (72.3%)	162 (83.1%)
Mean (SD)	-1.46 (2.39)	-0.64 (1.74)	-1.22 (2.25)
Median	-0.75	-0.38	-0.65
Q1, Q3	-3.06, 0.04	-1.57, 0.18	-2.68, 0.04
Min, Max	-8.3, 4.6	-5.3, 4.3	-8.3, 4.6
Least Squares Mean (SE) [1]	-1.31 (0.19)	-0.52 (0.28)	
95% CI [1]	-1.69, -0.92	-1.08, 0.03	
Least Squares Mean Difference (SE) [1]	-0.78 (0.34)		
95% CI [1]	-1.45, -0.12		
p-value [2]	0.021		
Corrected Hedges' g (95% CI)	-0.383 (-0.724, -0.041)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Table 2.0505: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Rib Pain

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	101 (77.7%)	40 (61.5%)	141 (72.3%)
Mean (SD)	-19.37 (135.28)	20.16 (300.55)	-8.15 (196.36)
Median	-49.15	-35.68	-41.56
Q1, Q3	-85.78, 0.00	-65.35, 0.22	-83.65, 0.00
Min, Max	-100.0, 1066.7	-100.0, 1825.0	-100.0, 1825.0
Return Rate (%)	88%	72%	
Number of Subjects in Risk	123	53	
Return Rate in Risk (%)	93%	89%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Study SRA-MMB-301

Table 2.0505: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Rib Pain

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 16			
n (%)	100 (76.9%)	40 (61.5%)	140 (71.8%)
Mean (SD)	1.85 (2.02)	2.09 (1.97)	1.92 (2.01)
Median	1.09	1.76	1.27
Q1, Q3	0.09, 2.96	0.24, 3.04	0.11, 3.00
Min, Max	0.0, 7.0	0.0, 7.0	0.0, 7.0
Change from Baseline			
n (%)	100 (76.9%)	40 (61.5%)	140 (71.8%)
Mean (SD)	-1.66 (2.66)	-0.49 (1.91)	-1.32 (2.52)
Median	-1.39	-0.25	-0.79
Q1, Q3	-3.25, 0.06	-1.75, 0.43	-2.71, 0.18
Min, Max	-8.1, 4.7	-5.3, 4.4	-8.1, 4.7
Least Squares Mean (SE) [1]	-1.38 (0.21)	-0.55 (0.31)	
95% CI [1]	-1.79, -0.96	-1.16, 0.06	
Least Squares Mean Difference (SE) [1]	-0.83 (0.37)		
95% CI [1]	-1.55, -0.10		
p-value [2]	0.025		
Corrected Hedges' g (95% CI)	-0.401 (-0.771, -0.031)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.0505: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Rib Pain

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	88 (67.7%)	35 (53.8%)	123 (63.1%)
Mean (SD)	-18.29 (149.39)	49.16 (344.69)	0.91 (223.52)
Median	-56.01	-24.38	-36.76
Q1, Q3	-89.84, 4.90	-71.39, 24.26	-86.25, 8.33
Min, Max	-100.0, 1066.7	-100.0, 1950.0	-100.0, 1950.0
Return Rate (%)	77%	62%	
Number of Subjects in Risk	113	48	
Return Rate in Risk (%)	88%	83%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Table 2.0505: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Rib Pain

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 20			
n (%)	100 (76.9%)	36 (55.4%)	136 (69.7%)
Mean (SD)	1.83 (1.99)	2.03 (2.14)	1.88 (2.03)
Median	1.16	1.50	1.17
Q1, Q3	0.09, 2.96	0.07, 3.04	0.09, 3.00
Min, Max	0.0, 7.0	0.0, 7.4	0.0, 7.4
Change from Baseline			
n (%)	100 (76.9%)	36 (55.4%)	136 (69.7%)
Mean (SD)	-1.62 (2.55)	-0.72 (1.89)	-1.38 (2.42)
Median	-1.05	-0.42	-0.86
Q1, Q3	-3.16, 0.02	-2.19, 0.37	-2.71, 0.11
Min, Max	-9.5, 4.9	-5.7, 4.4	-9.5, 4.9
Least Squares Mean (SE) [1]	-1.37 (0.21)	-0.59 (0.31)	
95% CI [1]	-1.79, -0.96	-1.21, 0.03	
Least Squares Mean Difference (SE) [1]	-0.78 (0.37)		
95% CI [1]	-1.51, -0.05		
p-value [2]	0.037		
Corrected Hedges' g (95% CI)	-0.379 (-0.763, 0.005)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t_tss_chg_rt24_gba.sas V.03.05 Output file: t-c-rib-g.pdf 13SEP2023: 8:35

Table 2.0505: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Rib Pain

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	88 (67.7%)	33 (50.8%)	121 (62.1%)
Mean (SD)	-25.95 (136.14)	39.16 (285.30)	-8.19 (189.71)
Median	-52.02	-18.90	-42.86
Q1, Q3	-90.83, -1.57	-86.84, 20.99	-90.67, 0.00
Min, Max	-100.0, 1076.0	-100.0, 1300.0	-100.0, 1300.0
Return Rate (%)	77%	55%	
Number of Subjects in Risk	106	42	
Return Rate in Risk (%)	94%	86%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t_tss_chg_rt24_gba.sas V.03.05 Output file: t-c-rib-g.pdf 13SEP2023: 8:35

GSK Oncology

Study SRA-MMB-301

Table 2.0505: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Rib Pain

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 24			
n (%)	92 (70.8%)	37 (56.9%)	129 (66.2%)
Mean (SD)	1.85 (2.07)	2.10 (2.17)	1.92 (2.10)
Median	1.02	1.79	1.22
Q1, Q3	0.04, 2.92	0.07, 3.07	0.07, 3.04
Min, Max	0.0, 7.0	0.0, 7.6	0.0, 7.6
Change from Baseline			
n (%)	92 (70.8%)	37 (56.9%)	129 (66.2%)
Mean (SD)	-1.69 (2.63)	-0.65 (1.80)	-1.39 (2.46)
Median	-1.11	-0.59	-0.82
Q1, Q3	-3.18, 0.00	-2.13, 0.25	-2.70, 0.00
Min, Max	-8.4, 5.0	-4.6, 4.7	-8.4, 5.0
Least Squares Mean (SE) [1]	-1.34 (0.21)	-0.54 (0.32)	
95% CI [1]	-1.76, -0.92	-1.17, 0.08	
Least Squares Mean Difference (SE) [1]	-0.80 (0.38)		
95% CI [1]	-1.54, -0.05		
p-value [2]	0.036		
Corrected Hedges' g (95% CI)	-0.393 (-0.778, -0.008)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

GSK Oncology

Study SRA-MMB-301

Table 2.0505: MFSAF Total Symptom Score (TSS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Rib Pain

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	82 (63.1%)	33 (50.8%)	115 (59.0%)
Mean (SD)	-29.87 (139.04)	60.38 (374.56)	-3.97 (234.09)
Median	-60.83	-35.83	-50.89
Q1, Q3	-93.00, -10.06	-88.89, 9.38	-91.07, -1.36
Min, Max	-100.0, 1101.2	-100.0, 1725.0	-100.0, 1725.0
Return Rate (%)	71%	57%	
Number of Subjects in Risk	99	39	
Return Rate in Risk (%)	93%	95%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

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Study SRA-MMB-301

Table 2.0401: MFSAF Total Symptom Score (TSS) Change From Baseline Over the 24-Week Randomized Treatment Period

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Total Symptom Score (TSS)			
Baseline			
n (%)	130 (100%)	65 (100%)	195 (100%)
Mean (SD)	27.96 (13.84)	25.70 (12.79)	27.21 (13.51)
Median	26.43	23.57	25.43
Q1, Q3	16.71, 38.00	15.33, 36.14	16.29, 36.86
Min, Max	5.2, 67.7	4.9, 53.7	4.9, 67.7
Return Rate (%)	100%	100%	
Number of Subjects in Risk	130	65	
Return Rate in Risk (%)	100%	100%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.0401: MFSAF Total Symptom Score (TSS) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 4			
n (%)	121 (93.1%)	56 (86.2%)	177 (90.8%)
Mean (SD)	21.82 (12.21)	22.85 (12.39)	22.15 (12.24)
Median	20.52	21.95	20.61
Q1, Q3	12.86, 28.33	14.78, 30.02	13.29, 29.14
Min, Max	0.6, 55.7	3.6, 53.3	0.6, 55.7
Change from Baseline			
n (%)	121 (93.1%)	56 (86.2%)	177 (90.8%)
Mean (SD)	-5.67 (8.15)	-2.34 (6.02)	-4.62 (7.68)
Median	-4.04	-1.23	-2.93
Q1, Q3	-10.54, -0.86	-5.95, 1.35	-8.84, -0.05
Min, Max	-35.0, 12.2	-19.5, 8.1	-35.0, 12.2
Least Squares Mean (SE) [1]	-5.49 (0.68)	-2.11 (0.97)	
95% CI [1]	-6.83, -4.15	-4.01, -0.20	
Least Squares Mean Difference (SE) [1]	-3.38 (1.14)		
95% CI [1]	-5.63, -1.13		
p-value [2]	0.003		
Corrected Hedges' g (95% CI)	-0.456 (-0.776, -0.135)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t_tss_chg_rt24_gba.sas V.03.05 Output file: t-c-rt24-g.pdf 13SEP2023: 8:35

Table 2.0401: MFSAF Total Symptom Score (TSS) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	121 (93.1%)	56 (86.2%)	177 (90.8%)
Mean (SD)	-17.41 (33.50)	-8.04 (26.19)	-14.45 (31.60)
Median	-18.21	-7.33	-13.78
Q1, Q3	-33.81, -3.62	-21.60, 5.06	-31.75, -0.26
Min, Max	-97.2, 132.7	-79.0, 56.2	-97.2, 132.7
Return Rate (%)	93%	86%	
Number of Subjects in Risk	130	65	
Return Rate in Risk (%)	93%	86%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t_tss_chg_rt24_gba.sas V.03.05 Output file: t-c-rt24-g.pdf 13SEP2023: 8:35

Table 2.0401: MFSAF Total Symptom Score (TSS) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 8			
n (%)	119 (91.5%)	54 (83.1%)	173 (88.7%)
Mean (SD)	18.81 (11.63)	21.80 (12.45)	19.74 (11.94)
Median	16.89	20.54	17.65
Q1, Q3	10.36, 25.81	13.68, 29.36	11.07, 27.50
Min, Max	0.2, 55.3	0.1, 52.5	0.1, 55.3
Change from Baseline			
n (%)	119 (91.5%)	54 (83.1%)	173 (88.7%)
Mean (SD)	-9.29 (11.10)	-3.72 (9.03)	-7.55 (10.78)
Median	-7.46	-1.72	-5.57
Q1, Q3	-14.79, -1.57	-8.26, 2.24	-13.25, -0.40
Min, Max	-48.2, 14.4	-24.3, 13.8	-48.2, 14.4
Least Squares Mean (SE) [1]	-8.53 (0.92)	-3.29 (1.32)	
95% CI [1]	-10.34, -6.72	-5.90, -0.68	
Least Squares Mean Difference (SE) [1]	-5.24 (1.58)		
95% CI [1]	-8.35, -2.12		
p-value [2]	0.001		
Corrected Hedges' g (95% CI)	-0.526 (-0.852, -0.199)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.0401: MFSAF Total Symptom Score (TSS) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	119 (91.5%)	54 (83.1%)	173 (88.7%)
Mean (SD)	-28.99 (36.21)	-11.55 (36.44)	-23.55 (37.07)
Median	-29.26	-10.26	-23.30
Q1, Q3	-55.12, -6.67	-35.06, 8.48	-49.99, -1.49
Min, Max	-97.8, 90.8	-99.6, 95.3	-99.6, 95.3
Return Rate (%)	92%	83%	
Number of Subjects in Risk	129	63	
Return Rate in Risk (%)	92%	86%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t_tss_chg_rt24_gba.sas V.03.05 Output file: t-c-rt24-g.pdf 13SEP2023: 8:35

Table 2.0401: MFSAF Total Symptom Score (TSS) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 12			
n (%)	115 (88.5%)	47 (72.3%)	162 (83.1%)
Mean (SD)	18.54 (11.68)	20.60 (12.12)	19.14 (11.81)
Median	16.00	18.04	16.32
Q1, Q3	10.14, 26.00	12.75, 26.96	10.85, 26.48
Min, Max	0.0, 56.5	0.2, 55.5	0.0, 56.5
Change from Baseline			
n (%)	115 (88.5%)	47 (72.3%)	162 (83.1%)
Mean (SD)	-9.91 (11.84)	-4.18 (9.75)	-8.24 (11.54)
Median	-7.63	-4.07	-6.21
Q1, Q3	-15.92, -1.59	-9.61, 0.64	-13.57, -0.61
Min, Max	-47.6, 11.0	-33.7, 20.4	-47.6, 20.4
Least Squares Mean (SE) [1]	-8.91 (0.97)	-3.72 (1.41)	
95% CI [1]	-10.82, -6.99	-6.51, -0.93	
Least Squares Mean Difference (SE) [1]	-5.19 (1.69)		
95% CI [1]	-8.52, -1.86		
p-value [2]	0.002		
Corrected Hedges' g (95% CI)	-0.506 (-0.850, -0.162)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.0401: MFSAF Total Symptom Score (TSS) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	115 (88.5%)	47 (72.3%)	162 (83.1%)
Mean (SD)	-29.73 (37.97)	-12.50 (39.60)	-24.73 (39.12)
Median	-29.39	-17.71	-25.85
Q1, Q3	-57.52, -6.96	-38.52, 8.23	-52.88, -2.83
Min, Max	-100.0, 104.9	-99.0, 122.4	-100.0, 122.4
Return Rate (%)	88%	72%	
Number of Subjects in Risk	123	53	
Return Rate in Risk (%)	93%	89%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t_tss_chg_rt24_gba.sas V.03.05 Output file: t-c-rt24-g.pdf 13SEP2023: 8:35

Table 2.0401: MFSAF Total Symptom Score (TSS) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 16			
n (%)	100 (76.9%)	40 (61.5%)	140 (71.8%)
Mean (SD)	17.51 (11.80)	21.38 (12.24)	18.62 (12.01)
Median	15.35	17.08	16.30
Q1, Q3	8.24, 24.20	14.04, 30.61	9.38, 25.71
Min, Max	1.0, 57.0	0.2, 56.9	0.2, 57.0
Change from Baseline			
n (%)	100 (76.9%)	40 (61.5%)	140 (71.8%)
Mean (SD)	-11.20 (12.44)	-2.87 (10.94)	-8.82 (12.57)
Median	-8.51	-3.39	-6.93
Q1, Q3	-16.84, -2.26	-8.13, 2.46	-14.30, -0.90
Min, Max	-47.6, 12.1	-35.2, 21.7	-47.6, 21.7
Least Squares Mean (SE) [1]	-9.17 (1.03)	-3.41 (1.51)	
95% CI [1]	-11.20, -7.14	-6.39, -0.43	
Least Squares Mean Difference (SE) [1]	-5.76 (1.80)		
95% CI [1]	-9.31, -2.20		
p-value [2]	0.002		
Corrected Hedges' g (95% CI)	-0.568 (-0.941, -0.195)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.0401: MFSAF Total Symptom Score (TSS) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	100 (76.9%)	40 (61.5%)	140 (71.8%)
Mean (SD)	-33.34 (40.49)	-4.51 (45.62)	-25.10 (43.84)
Median	-37.24	-11.97	-27.09
Q1, Q3	-63.72, -9.01	-29.72, 23.42	-60.53, -4.03
Min, Max	-93.6, 161.2	-99.1, 111.9	-99.1, 161.2
Return Rate (%)	77%	62%	
Number of Subjects in Risk	113	48	
Return Rate in Risk (%)	88%	83%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t_tss_chg_rt24_gba.sas V.03.05 Output file: t-c-rt24-g.pdf 13SEP2023: 8:35

Table 2.0401: MFSAF Total Symptom Score (TSS) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 20			
n (%)	100 (76.9%)	36 (55.4%)	136 (69.7%)
Mean (SD)	17.51 (11.33)	20.73 (13.03)	18.36 (11.84)
Median	15.67	17.09	15.79
Q1, Q3	8.23, 23.02	12.20, 27.24	9.45, 24.28
Min, Max	1.9, 56.8	0.9, 56.9	0.9, 56.9
Change from Baseline			
n (%)	100 (76.9%)	36 (55.4%)	136 (69.7%)
Mean (SD)	-10.82 (12.33)	-4.02 (11.84)	-9.02 (12.52)
Median	-9.16	-3.15	-6.90
Q1, Q3	-17.22, -1.46	-8.85, 2.43	-14.61, -0.85
Min, Max	-47.2, 13.0	-35.4, 21.7	-47.2, 21.7
Least Squares Mean (SE) [1]	-9.41 (1.06)	-3.18 (1.58)	
95% CI [1]	-11.50, -7.31	-6.30, -0.06	
Least Squares Mean Difference (SE) [1]	-6.23 (1.88)		
95% CI [1]	-9.93, -2.52		
p-value [2]	0.001		
Corrected Hedges' g (95% CI)	-0.599 (-0.987, -0.212)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.0401: MFSAF Total Symptom Score (TSS) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	100 (76.9%)	36 (55.4%)	136 (69.7%)
Mean (SD)	-32.03 (39.03)	-8.95 (47.30)	-25.92 (42.45)
Median	-37.51	-8.93	-30.07
Q1, Q3	-60.44, -7.20	-36.78, 17.08	-55.26, -3.41
Min, Max	-90.0, 172.7	-96.1, 89.9	-96.1, 172.7
Return Rate (%)	77%	55%	
Number of Subjects in Risk	106	42	
Return Rate in Risk (%)	94%	86%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t_tss_chg_rt24_gba.sas V.03.05 Output file: t-c-rt24-g.pdf 13SEP2023: 8:35

Table 2.0401: MFSAF Total Symptom Score (TSS) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Week 24			
n (%)	92 (70.8%)	37 (56.9%)	129 (66.2%)
Mean (SD)	17.69 (11.86)	21.21 (13.47)	18.70 (12.40)
Median	15.72	16.96	16.18
Q1, Q3	8.49, 23.13	11.50, 27.65	9.17, 24.71
Min, Max	0.6, 56.6	0.1, 57.9	0.1, 57.9
Change from Baseline			
n (%)	92 (70.8%)	37 (56.9%)	129 (66.2%)
Mean (SD)	-11.52 (12.86)	-3.93 (11.94)	-9.34 (13.02)
Median	-9.39	-3.41	-7.21
Q1, Q3	-18.18, -2.34	-9.50, 0.82	-14.86, -1.36
Min, Max	-47.3, 12.3	-35.1, 22.8	-47.3, 22.8
Least Squares Mean (SE) [1]	-9.36 (1.08)	-3.13 (1.62)	
95% CI [1]	-11.50, -7.22	-6.32, 0.06	
Least Squares Mean Difference (SE) [1]	-6.22 (1.92)		
95% CI [1]	-10.02, -2.43		
p-value [2]	0.001		
Corrected Hedges' g (95% CI)	-0.604 (-0.993, -0.216)		

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

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Table 2.0401: MFSAF Total Symptom Score (TSS) Change From Baseline Over the 24-Week Randomized Treatment Period

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)	Total (N=195)
Percent Change from Baseline			
n (%)	92 (70.8%)	37 (56.9%)	129 (66.2%)
Mean (SD)	-33.40 (40.26)	-10.90 (49.73)	-26.95 (44.18)
Median	-38.08	-17.53	-33.97
Q1, Q3	-65.24, -11.62	-45.92, 5.08	-56.17, -3.96
Min, Max	-96.5, 163.8	-99.5, 127.4	-99.5, 163.8
Return Rate (%)	71%	57%	
Number of Subjects in Risk	99	39	
Return Rate in Risk (%)	93%	95%	

Notes: MFSAF = Myelofibrosis Symptom Assessment Form (MFSAF) v4.0.

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

3.3 Transfusionen

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Table 2.0202: Proportion of Subjects with Zero RBC Units Transfused Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set Who are Transfusion Dependent at Baseline

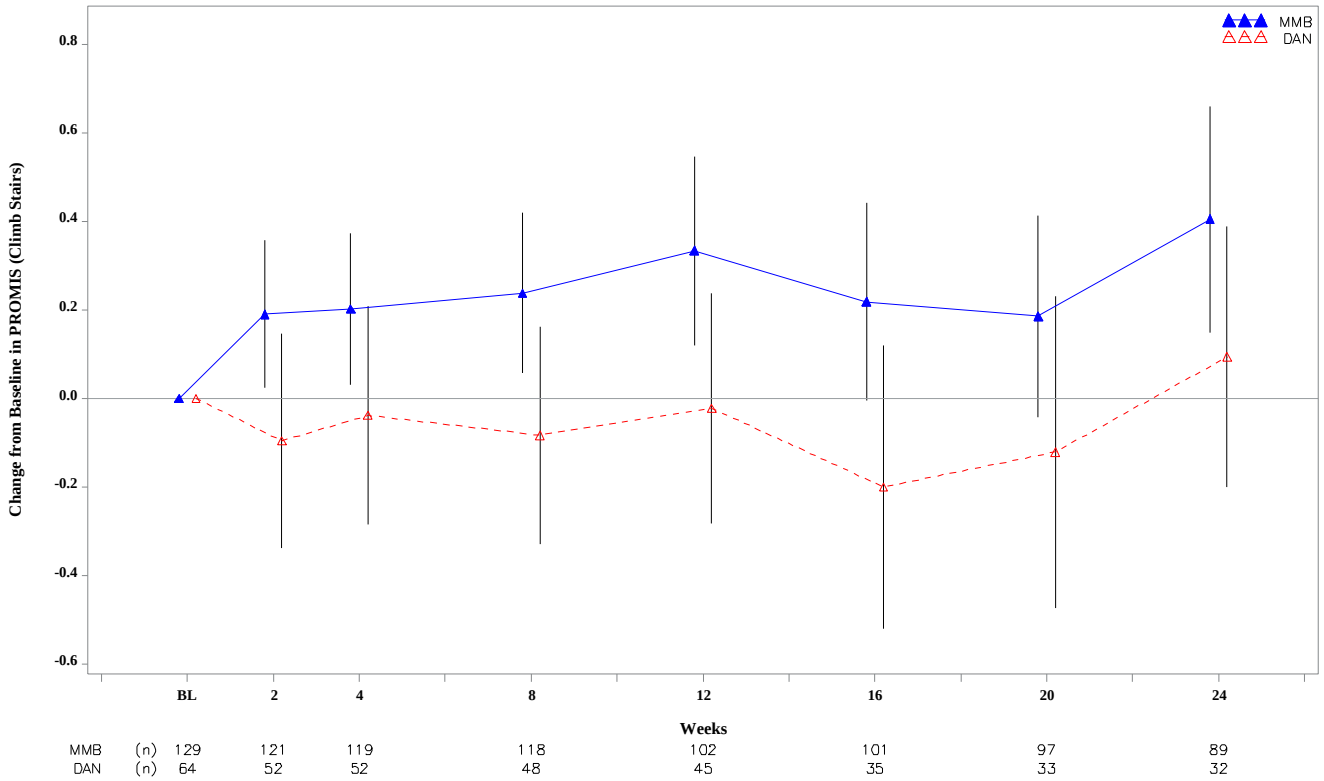
	MMB (N=63)	DAN (N=34)	Total (N=97)
Zero RBC transfusions			
Responder, n(%)	9 (14.3%)	0	9 (9.3%)
95% Exact CI [1]	14.29 (6.75, 25.39)	0.00 (0.00, 10.28)	
Difference (95% CI)			
Unstratified Exact [2]	14.29 (0.91, 25.39)		
Stratified CMH	12.15 (3.63, 20.66)		
p-value from stratified CMH test	0.048		
Unadjusted Inverse Relative Risk (95% CI)	0.10 (0.01, 1.60)		
p-value [3]	0.10		
Unadjusted Inverse Odds Ratio (95% CI)	0.08 (0.00, 1.47)		
p-value [3]	0.090		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (0.04, 0.23)		
Adjusted Inverse Relative Risk (95% CI) [4]	NE		
p-value [4]	NE		
Non-Responder, n(%)	54 (85.7%)	34 (100.0%)	88 (90.7%)

CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] Exact binomial confidence interval.
[2] 95% Exact CI is based on Clopper-Pearson method without stratification.
[3] p-values were from a Z-test.
[4] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model with robust sandwich matrix estimators, including treatment, Baseline MFSAF TSS (<22, >=22), Baseline palpable spleen length below the left costal margin (<12cm, >=12cm) and Baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+) as covariates.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-p-tf.sas V.03.05 Output file: t-p-tf-td.pdf 31AUG2023:16:00

3.4 PROMIS

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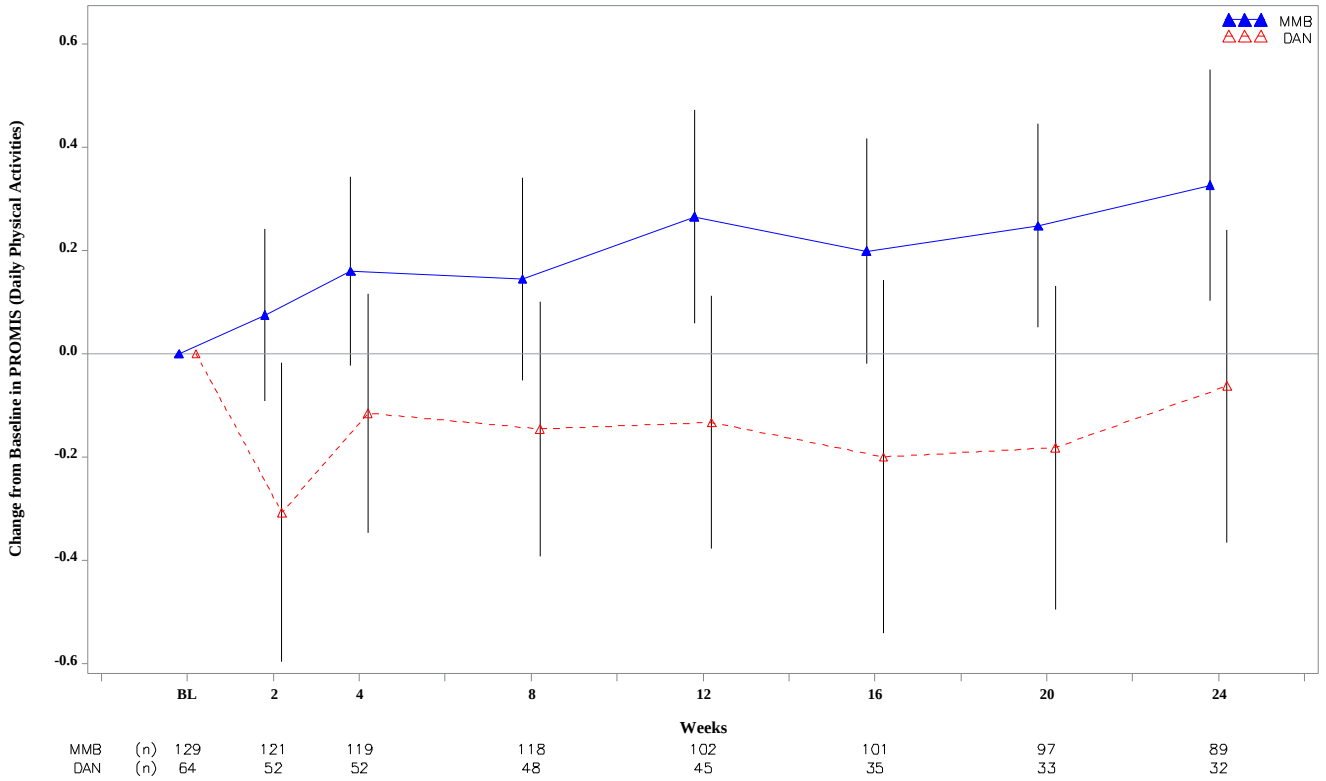
Figure 2.0601: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Climb Stairs Item Score (PROMIS)
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set



		BL	2	4	8	12	16	20	24
MMB	(n)	129	121	119	118	102	101	97	89
DAN	(n)	64	52	52	48	45	35	33	32

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-promis-chg-gbo.sas V.03.05 Output file: g-promis-cs.pdf 31AUG2023:15:26

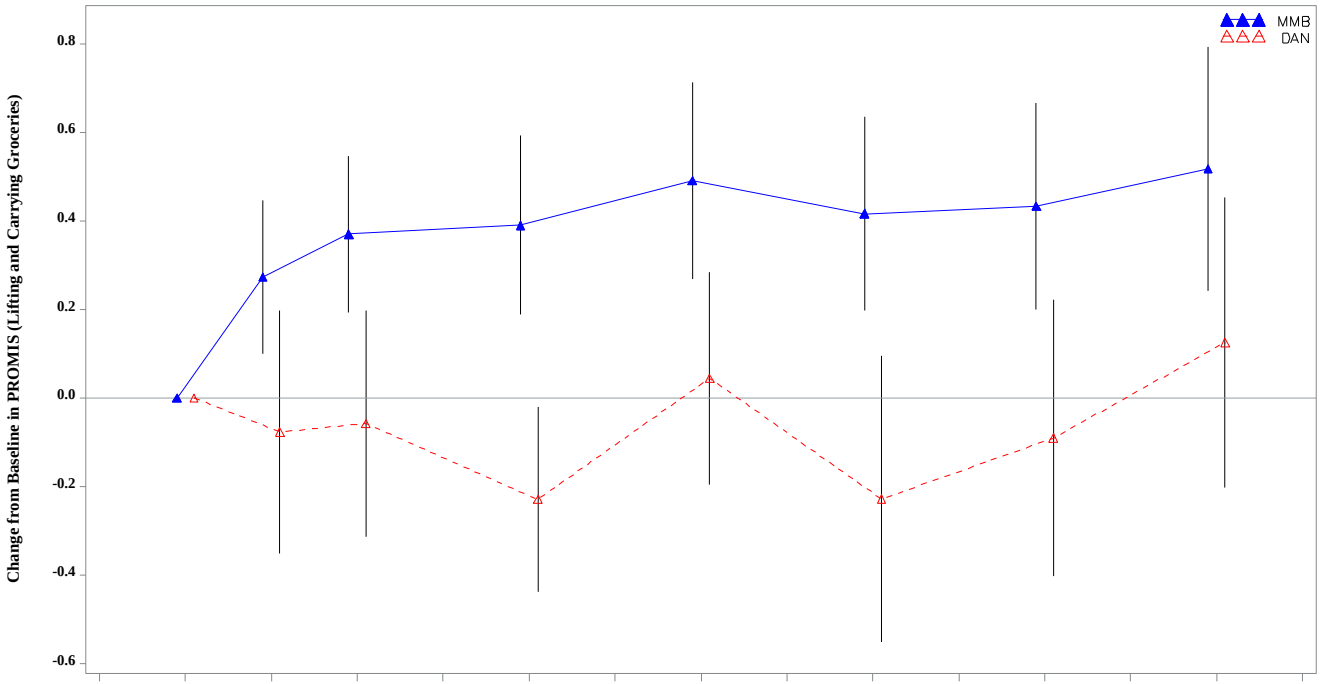
Figure 2.0604: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Daily Physical Activities Item Score (PROMIS)
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set



		BL	2	4	8	12	16	20	24
MMB	(n)	129	121	119	118	102	101	97	89
DAN	(n)	64	52	52	48	45	35	33	32

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-promis-chg-gba.sas V.03.05 Output file: g-promis-dpa.pdf 31AUG2023:15:26

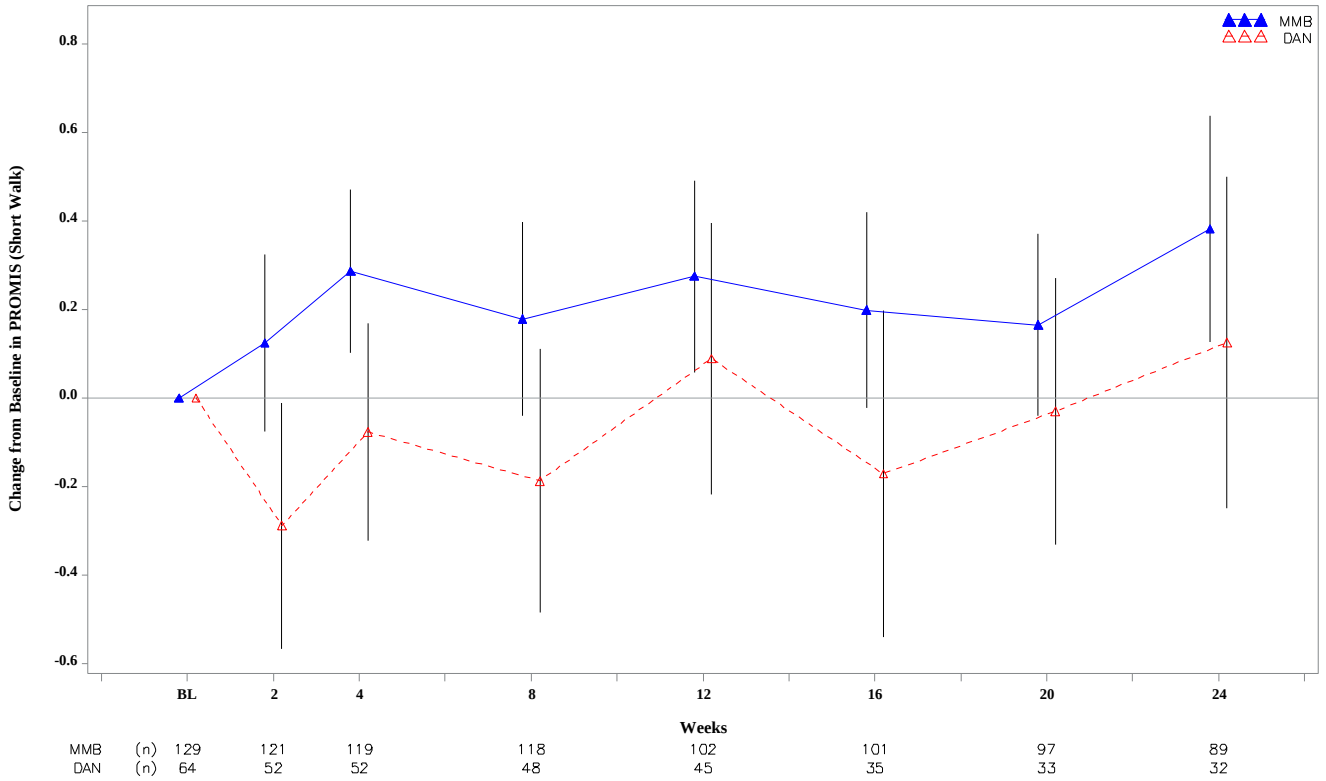
Figure 2.0602: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Lifting and Carrying Groceries Item Score (PROMIS)
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set



		BL	2	4	8	12	16	20	24
MMB	(n)	129	121	119	118	102	101	97	89
DAN	(n)	64	52	52	48	45	35	33	32

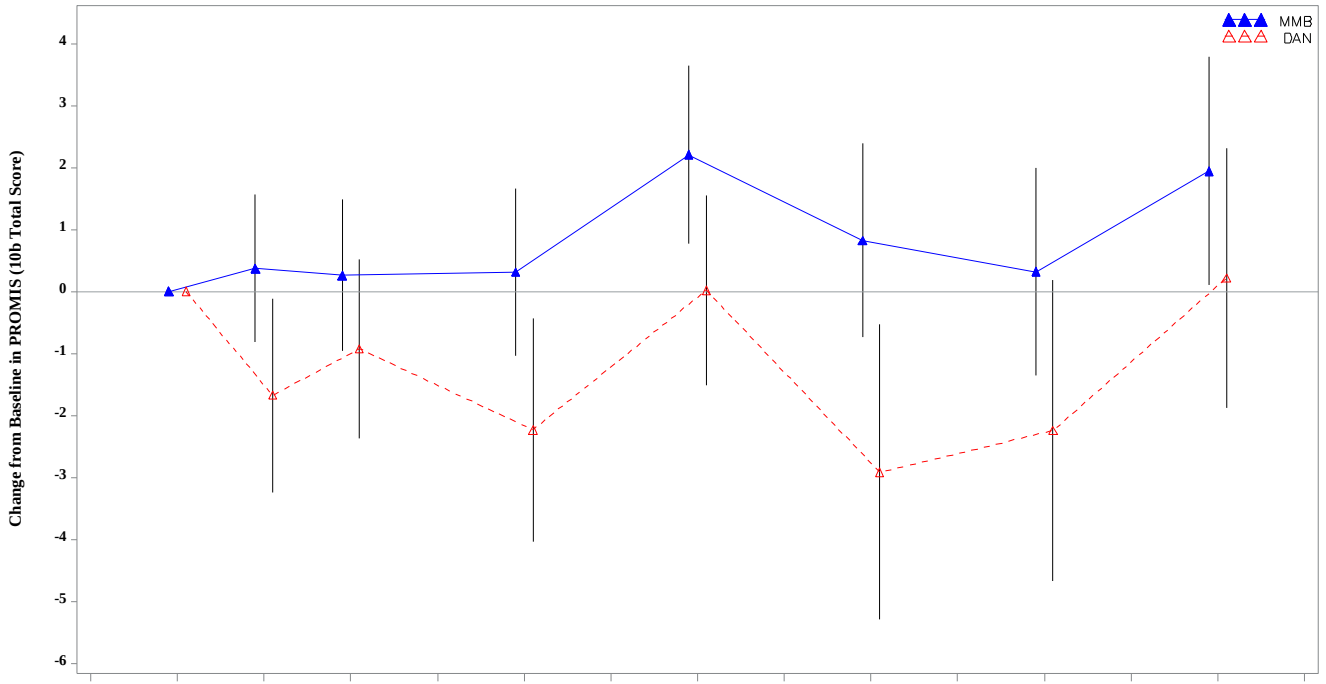
Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-promis-chg-gba.sas V.03.05 Output file: g-promis-lacg.pdf 31AUG2023:15:26

Figure 2.0603: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Short Walk Item Score (PROMIS)
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set



Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-promis-chg-gba.sas V.03.05 Output file: g-promis-sw.pdf 31AUG2023:15:26

Figure 2.0501: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Physical Function (PROMIS) 10b Total Score
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set



		BL	2	4	8	12	16	20	24
MMB	(n)	129	121	119	118	102	101	97	89
DAN	(n)	64	52	52	48	45	35	33	32

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-promis-chg-gba.sas V.03.05 Output file: g-promis-tot.pdf 31AUG2023:15:26

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Table 2.1101: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Climb Stairs

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Climb Stairs Item Score		
Baseline		
n (%)	129 (99.2%)	64 (98.5%)
Mean (SD)	2.33 (1.11)	2.59 (1.18)
Median	2.00	3.00
Q1, Q3	1.00, 3.00	2.00, 3.50
Min, Max	1.0, 5.0	1.0, 5.0
Return Rate (%)	99%	98%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	99%	98%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1101: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Climb Stairs
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 2		
n (%)	122 (93.8%)	53 (81.5%)
Mean (SD)	2.47 (1.08)	2.45 (1.25)
Median	2.00	2.00
Q1, Q3	2.00, 3.00	1.00, 3.00
Min, Max	1.0, 5.0	1.0, 5.0
Change from Baseline		
n (%)	121 (93.1%)	52 (80.0%)
Mean (SD)	0.19 (0.92)	-0.10 (0.87)
Median	0.00	0.00
Q1, Q3	0.00, 1.00	-1.00, 0.00
Min, Max	-2.0, 3.0	-2.0, 3.0
Least Squares Mean (SE) [1]	0.18 (0.09)	-0.07 (0.13)
95% CI [1]	0.01, 0.35	-0.32, 0.17
Least Squares Mean Difference (SE) [1]	0.26 (0.15)	
95% CI [1]	-0.03, 0.55	
p-value [2]	0.083	
Corrected Hedges' g (95% CI)	0.274 (-0.052, 0.601)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Study SRA-MMB-301

Table 2.1101: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Climb Stairs

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	121 (93.1%)	52 (80.0%)
Mean (SD)	21.13 (60.81)	0.77 (39.41)
Median	0.00	0.00
Q1, Q3	0.00, 50.00	-22.50, 0.00
Min, Max	-66.7, 300.0	-66.7, 150.0
Return Rate (%)	94%	82%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	94%	82%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

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Study SRA-MMB-301

Table 2.1101: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Climb Stairs

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 4		
n (%)	120 (92.3%)	53 (81.5%)
Mean (SD)	2.48 (1.17)	2.64 (1.16)
Median	2.00	3.00
Q1, Q3	1.00, 3.00	2.00, 4.00
Min, Max	1.0, 5.0	1.0, 5.0
Change from Baseline		
n (%)	119 (91.5%)	52 (80.0%)
Mean (SD)	0.20 (0.94)	-0.04 (0.88)
Median	0.00	0.00
Q1, Q3	0.00, 1.00	0.00, 0.00
Min, Max	-2.0, 3.0	-2.0, 3.0
Least Squares Mean (SE) [1]	0.17 (0.09)	-0.02 (0.13)
95% CI [1]	0.00, 0.34	-0.27, 0.24
Least Squares Mean Difference (SE) [1]	0.18 (0.15)	
95% CI [1]	-0.11, 0.48	
p-value [2]	0.22	
Corrected Hedges' g (95% CI)	0.195 (-0.132, 0.521)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.1101: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Climb Stairs
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	119 (91.5%)	52 (80.0%)
Mean (SD)	19.69 (60.20)	4.55 (41.95)
Median	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
Min, Max	-66.7, 300.0	-66.7, 150.0
Return Rate (%)	92%	82%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	92%	82%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-promis.sas V.03.05 Output file: t-promis-cs.pdf 31AUG2023:16:01

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Table 2.1101: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Climb Stairs

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 8		
n (%)	119 (91.5%)	49 (75.4%)
Mean (SD)	2.58 (1.20)	2.55 (1.21)
Median	3.00	2.00
Q1, Q3	2.00, 4.00	2.00, 3.00
Min, Max	1.0, 5.0	1.0, 5.0
Change from Baseline		
n (%)	118 (90.8%)	48 (73.8%)
Mean (SD)	0.24 (0.99)	-0.08 (0.85)
Median	0.00	0.00
Q1, Q3	0.00, 1.00	-0.50, 0.00
Min, Max	-2.0, 3.0	-2.0, 3.0
Least Squares Mean (SE) [1]	0.22 (0.09)	-0.07 (0.13)
95% CI [1]	0.04, 0.40	-0.34, 0.19
Least Squares Mean Difference (SE) [1]	0.29 (0.16)	
95% CI [1]	-0.02, 0.60	
p-value [2]	0.066	
Corrected Hedges' g (95% CI)	0.300 (-0.037, 0.637)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.1101: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Climb Stairs
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	118 (90.8%)	48 (73.8%)
Mean (SD)	21.51 (61.14)	0.80 (39.36)
Median	0.00	0.00
Q1, Q3	0.00, 33.33	-10.00, 0.00
Min, Max	-66.7, 300.0	-66.7, 150.0
Return Rate (%)	92%	75%
Number of Subjects in Risk	129	63
Return Rate in Risk (%)	92%	78%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-promis.sas V.03.05 Output file: t-promis-cs.pdf 31AUG2023:16:01

Table 2.1101: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Climb Stairs
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 12		
n (%)	103 (79.2%)	46 (70.8%)
Mean (SD)	2.72 (1.22)	2.78 (1.26)
Median	3.00	3.00
Q1, Q3	2.00, 4.00	2.00, 4.00
Min, Max	1.0, 5.0	1.0, 5.0
Change from Baseline		
n (%)	102 (78.5%)	45 (69.2%)
Mean (SD)	0.33 (1.08)	-0.02 (0.87)
Median	0.00	0.00
Q1, Q3	0.00, 1.00	0.00, 0.00
Min, Max	-2.0, 3.0	-2.0, 3.0
Least Squares Mean (SE) [1]	0.29 (0.10)	-0.02 (0.15)
95% CI [1]	0.10, 0.49	-0.31, 0.26
Least Squares Mean Difference (SE) [1]	0.32 (0.17)	
95% CI [1]	-0.02, 0.66	
p-value [2]	0.068	
Corrected Hedges' g (95% CI)	0.317 (-0.035, 0.670)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.1101: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Climb Stairs
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	102 (78.5%)	45 (69.2%)
Mean (SD)	28.48 (70.76)	0.85 (33.76)
Median	0.00	0.00
Q1, Q3	0.00, 50.00	0.00, 0.00
Min, Max	-66.7, 300.0	-66.7, 150.0
Return Rate (%)	79%	71%
Number of Subjects in Risk	121	52
Return Rate in Risk (%)	85%	88%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-promis.sas V.03.05 Output file: t-promis-cs.pdf 31AUG2023:16:01

Table 2.1101: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Climb Stairs
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 16		
n (%)	102 (78.5%)	36 (55.4%)
Mean (SD)	2.60 (1.16)	2.64 (1.20)
Median	3.00	2.50
Q1, Q3	2.00, 4.00	2.00, 4.00
Min, Max	1.0, 5.0	1.0, 5.0
Change from Baseline		
n (%)	101 (77.7%)	35 (53.8%)
Mean (SD)	0.22 (1.13)	-0.20 (0.93)
Median	0.00	0.00
Q1, Q3	0.00, 1.00	-1.00, 0.00
Min, Max	-4.0, 3.0	-2.0, 3.0
Least Squares Mean (SE) [1]	0.16 (0.10)	-0.23 (0.16)
95% CI [1]	-0.05, 0.36	-0.54, 0.09
Least Squares Mean Difference (SE) [1]	0.38 (0.19)	
95% CI [1]	0.01, 0.75	
p-value [2]	0.043	
Corrected Hedges' g (95% CI)	0.376 (-0.011, 0.763)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.1101: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Climb Stairs
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	101 (77.7%)	35 (53.8%)
Mean (SD)	24.09 (66.77)	-2.48 (39.26)
Median	0.00	0.00
Q1, Q3	0.00, 50.00	-25.00, 0.00
Min, Max	-80.0, 300.0	-66.7, 150.0
Return Rate (%)	78%	55%
Number of Subjects in Risk	113	48
Return Rate in Risk (%)	90%	75%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1101: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Climb Stairs
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 20		
n (%)	98 (75.4%)	33 (50.8%)
Mean (SD)	2.56 (1.11)	2.67 (1.19)
Median	3.00	2.00
Q1, Q3	2.00, 3.00	2.00, 4.00
Min, Max	1.0, 5.0	1.0, 5.0
Change from Baseline		
n (%)	97 (74.6%)	33 (50.8%)
Mean (SD)	0.19 (1.13)	-0.12 (0.99)
Median	0.00	0.00
Q1, Q3	0.00, 1.00	-1.00, 0.00
Min, Max	-4.0, 4.0	-2.0, 3.0
Least Squares Mean (SE) [1]	0.11 (0.11)	-0.24 (0.17)
95% CI [1]	-0.10, 0.32	-0.58, 0.10
Least Squares Mean Difference (SE) [1]	0.35 (0.20)	
95% CI [1]	-0.05, 0.74	
p-value [2]	0.082	
Corrected Hedges' g (95% CI)	0.334 (-0.063, 0.731)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.1101: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Climb Stairs
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	97 (74.6%)	33 (50.8%)
Mean (SD)	23.37 (69.95)	0.81 (40.52)
Median	0.00	0.00
Q1, Q3	0.00, 50.00	-33.33, 0.00
Min, Max	-80.0, 400.0	-66.7, 150.0
Return Rate (%)	75%	51%
Number of Subjects in Risk	107	41
Return Rate in Risk (%)	92%	80%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1101: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Climb Stairs
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 24		
n (%)	90 (69.2%)	33 (50.8%)
Mean (SD)	2.71 (1.18)	2.79 (1.17)
Median	3.00	3.00
Q1, Q3	2.00, 4.00	2.00, 4.00
Min, Max	1.0, 5.0	1.0, 5.0
Change from Baseline		
n (%)	89 (68.5%)	32 (49.2%)
Mean (SD)	0.40 (1.21)	0.09 (0.82)
Median	0.00	0.00
Q1, Q3	0.00, 1.00	0.00, 0.50
Min, Max	-4.0, 4.0	-1.0, 2.0
Least Squares Mean (SE) [1]	0.33 (0.11)	-0.03 (0.18)
95% CI [1]	0.11, 0.56	-0.38, 0.32
Least Squares Mean Difference (SE) [1]	0.36 (0.21)	
95% CI [1]	-0.05, 0.78	
p-value [2]	0.083	
Corrected Hedges' g (95% CI)	0.344 (-0.062, 0.751)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Study SRA-MMB-301

Table 2.1101: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Climb Stairs

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	89 (68.5%)	32 (49.2%)
Mean (SD)	35.11 (79.14)	8.33 (41.42)
Median	0.00	0.00
Q1, Q3	0.00, 66.67	0.00, 12.50
Min, Max	-80.0, 400.0	-50.0, 100.0
Return Rate (%)	69%	51%
Number of Subjects in Risk	101	39
Return Rate in Risk (%)	89%	85%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

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Study SRA-MMB-301

Table 2.1104: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Daily Physical Activities

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Daily Physical Activities Item Score		
Baseline		
n (%)	129 (99.2%)	64 (98.5%)
Mean (SD)	2.99 (1.03)	3.23 (1.07)
Median	3.00	3.50
Q1, Q3	2.00, 4.00	2.50, 4.00
Min, Max	1.0, 5.0	1.0, 5.0
Return Rate (%)	99%	98%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	99%	98%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.1104: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Daily Physical Activities
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 2		
n (%)	122 (93.8%)	53 (81.5%)
Mean (SD)	3.02 (0.99)	3.00 (1.24)
Median	3.00	3.00
Q1, Q3	2.00, 4.00	2.00, 4.00
Min, Max	1.0, 5.0	1.0, 5.0
Change from Baseline		
n (%)	121 (93.1%)	52 (80.0%)
Mean (SD)	0.07 (0.92)	-0.31 (1.04)
Median	0.00	0.00
Q1, Q3	0.00, 1.00	-1.00, 0.00
Min, Max	-2.0, 3.0	-3.0, 2.0
Least Squares Mean (SE) [1]	0.06 (0.09)	-0.28 (0.13)
95% CI [1]	-0.11, 0.24	-0.54, -0.02
Least Squares Mean Difference (SE) [1]	0.34 (0.16)	
95% CI [1]	0.03, 0.65	
p-value [2]	0.030	
Corrected Hedges' g (95% CI)	0.347 (0.020, 0.674)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Study SRA-MMB-301

Table 2.1104: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Daily Physical Activities

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	121 (93.1%)	52 (80.0%)
Mean (SD)	9.35 (42.30)	-5.64 (40.41)
Median	0.00	0.00
Q1, Q3	0.00, 33.33	-25.00, 0.00
Min, Max	-50.0, 300.0	-75.0, 200.0
Return Rate (%)	94%	82%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	94%	82%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

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Study SRA-MMB-301

Table 2.1104: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Daily Physical Activities

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 4		
n (%)	120 (92.3%)	53 (81.5%)
Mean (SD)	3.13 (1.04)	3.21 (1.10)
Median	3.00	3.00
Q1, Q3	2.00, 4.00	2.00, 4.00
Min, Max	1.0, 5.0	1.0, 5.0
Change from Baseline		
n (%)	119 (91.5%)	52 (80.0%)
Mean (SD)	0.16 (1.01)	-0.12 (0.83)
Median	0.00	0.00
Q1, Q3	0.00, 1.00	-1.00, 0.00
Min, Max	-2.0, 3.0	-2.0, 2.0
Least Squares Mean (SE) [1]	0.16 (0.09)	-0.10 (0.13)
95% CI [1]	-0.01, 0.33	-0.35, 0.15
Least Squares Mean Difference (SE) [1]	0.26 (0.15)	
95% CI [1]	-0.04, 0.55	
p-value [2]	0.088	
Corrected Hedges' g (95% CI)	0.273 (-0.054, 0.600)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.1104: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Daily Physical Activities
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	119 (91.5%)	52 (80.0%)
Mean (SD)	13.67 (48.34)	0.83 (40.70)
Median	0.00	0.00
Q1, Q3	0.00, 33.33	-25.00, 0.00
Min, Max	-50.0, 300.0	-50.0, 200.0
Return Rate (%)	92%	82%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	92%	82%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-promis.sas V.03.05 Output file: t-promis-dpa.pdf 31AUG2023:16:01

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Study SRA-MMB-301

Table 2.1104: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Daily Physical Activities

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 8		
n (%)	119 (91.5%)	49 (75.4%)
Mean (SD)	3.15 (1.05)	3.14 (1.12)
Median	3.00	3.00
Q1, Q3	2.00, 4.00	2.00, 4.00
Min, Max	1.0, 5.0	1.0, 5.0
Change from Baseline		
n (%)	118 (90.8%)	48 (73.8%)
Mean (SD)	0.14 (1.07)	-0.15 (0.85)
Median	0.00	0.00
Q1, Q3	0.00, 1.00	-1.00, 0.00
Min, Max	-3.0, 3.0	-2.0, 2.0
Least Squares Mean (SE) [1]	0.12 (0.10)	-0.24 (0.14)
95% CI [1]	-0.07, 0.31	-0.52, 0.05
Least Squares Mean Difference (SE) [1]	0.36 (0.17)	
95% CI [1]	0.02, 0.69	
p-value [2]	0.035	
Corrected Hedges' g (95% CI)	0.347 (0.009, 0.685)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.1104: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Daily Physical Activities
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	118 (90.8%)	48 (73.8%)
Mean (SD)	14.75 (55.15)	-0.24 (41.13)
Median	0.00	0.00
Q1, Q3	0.00, 33.33	-25.00, 0.00
Min, Max	-75.0, 300.0	-66.7, 200.0
Return Rate (%)	92%	75%
Number of Subjects in Risk	129	63
Return Rate in Risk (%)	92%	78%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-promis.sas V.03.05 Output file: t-promis-dpa.pdf 31AUG2023:16:01

Table 2.1104: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Daily Physical Activities
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 12		
n (%)	103 (79.2%)	46 (70.8%)
Mean (SD)	3.26 (1.08)	3.30 (1.09)
Median	3.00	3.00
Q1, Q3	2.00, 4.00	3.00, 4.00
Min, Max	1.0, 5.0	1.0, 5.0
Change from Baseline		
n (%)	102 (78.5%)	45 (69.2%)
Mean (SD)	0.26 (1.05)	-0.13 (0.81)
Median	0.00	0.00
Q1, Q3	0.00, 1.00	-1.00, 0.00
Min, Max	-2.0, 3.0	-2.0, 1.0
Least Squares Mean (SE) [1]	0.22 (0.09)	-0.17 (0.14)
95% CI [1]	0.03, 0.40	-0.44, 0.10
Least Squares Mean Difference (SE) [1]	0.39 (0.16)	
95% CI [1]	0.06, 0.71	
p-value [2]	0.019	
Corrected Hedges' g (95% CI)	0.409 (0.055, 0.763)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.1104: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Daily Physical Activities
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	102 (78.5%)	45 (69.2%)
Mean (SD)	17.61 (56.07)	-3.33 (23.60)
Median	0.00	0.00
Q1, Q3	0.00, 33.33	-25.00, 0.00
Min, Max	-66.7, 300.0	-66.7, 50.0
Return Rate (%)	79%	71%
Number of Subjects in Risk	121	52
Return Rate in Risk (%)	85%	88%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-promis.sas V.03.05 Output file: t-promis-dpa.pdf 31AUG2023:16:01

GSK Oncology

Study SRA-MMB-301

Table 2.1104: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Daily Physical Activities

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 16		
n (%)	102 (78.5%)	36 (55.4%)
Mean (SD)	3.18 (1.15)	3.31 (1.06)
Median	3.00	3.00
Q1, Q3	2.00, 4.00	2.50, 4.00
Min, Max	1.0, 5.0	1.0, 5.0
Change from Baseline		
n (%)	101 (77.7%)	35 (53.8%)
Mean (SD)	0.20 (1.10)	-0.20 (0.99)
Median	0.00	0.00
Q1, Q3	-1.00, 1.00	-1.00, 0.00
Min, Max	-2.0, 4.0	-2.0, 2.0
Least Squares Mean (SE) [1]	0.06 (0.11)	-0.24 (0.17)
95% CI [1]	-0.15, 0.28	-0.57, 0.10
Least Squares Mean Difference (SE) [1]	0.30 (0.20)	
95% CI [1]	-0.09, 0.69	
p-value [2]	0.13	
Corrected Hedges' g (95% CI)	0.282 (-0.104, 0.668)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1104: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Daily Physical Activities
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	101 (77.7%)	35 (53.8%)
Mean (SD)	16.96 (65.07)	-4.14 (29.29)
Median	0.00	0.00
Q1, Q3	-20.00, 33.33	-25.00, 0.00
Min, Max	-66.7, 400.0	-50.0, 66.7
Return Rate (%)	78%	55%
Number of Subjects in Risk	113	48
Return Rate in Risk (%)	90%	75%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-promis.sas V.03.05 Output file: t-promis-dpa.pdf 31AUG2023:16:01

GSK Oncology
Study SRA-MMB-301

Table 2.1104: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Daily Physical Activities
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 20		
n (%)	98 (75.4%)	33 (50.8%)
Mean (SD)	3.19 (1.10)	3.36 (0.99)
Median	3.00	3.00
Q1, Q3	2.00, 4.00	3.00, 4.00
Min, Max	1.0, 5.0	1.0, 5.0
Change from Baseline		
n (%)	97 (74.6%)	33 (50.8%)
Mean (SD)	0.25 (0.98)	-0.18 (0.88)
Median	0.00	0.00
Q1, Q3	0.00, 1.00	-1.00, 0.00
Min, Max	-2.0, 3.0	-2.0, 2.0
Least Squares Mean (SE) [1]	0.08 (0.09)	-0.26 (0.15)
95% CI [1]	-0.10, 0.27	-0.55, 0.03
Least Squares Mean Difference (SE) [1]	0.35 (0.17)	
95% CI [1]	0.01, 0.68	
p-value [2]	0.042	
Corrected Hedges' g (95% CI)	0.385 (-0.013, 0.783)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1104: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Daily Physical Activities
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	97 (74.6%)	33 (50.8%)
Mean (SD)	16.82 (52.88)	-3.99 (25.89)
Median	0.00	0.00
Q1, Q3	0.00, 33.33	-25.00, 0.00
Min, Max	-66.7, 300.0	-50.0, 66.7
Return Rate (%)	75%	51%
Number of Subjects in Risk	107	41
Return Rate in Risk (%)	92%	80%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-promis.sas V.03.05 Output file: t-promis-dpa.pdf 31AUG2023:16:01

GSK Oncology

Study SRA-MMB-301

Table 2.1104: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Daily Physical Activities

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 24		
n (%)	90 (69.2%)	33 (50.8%)
Mean (SD)	3.30 (1.13)	3.42 (1.09)
Median	3.50	4.00
Q1, Q3	3.00, 4.00	3.00, 4.00
Min, Max	1.0, 5.0	1.0, 5.0
Change from Baseline		
n (%)	89 (68.5%)	32 (49.2%)
Mean (SD)	0.33 (1.06)	-0.06 (0.84)
Median	0.00	0.00
Q1, Q3	0.00, 1.00	0.00, 0.00
Min, Max	-2.0, 3.0	-2.0, 2.0
Least Squares Mean (SE) [1]	0.20 (0.10)	-0.13 (0.17)
95% CI [1]	0.00, 0.41	-0.46, 0.20
Least Squares Mean Difference (SE) [1]	0.33 (0.19)	
95% CI [1]	-0.05, 0.72	
p-value [2]	0.088	
Corrected Hedges' g (95% CI)	0.339 (-0.068, 0.745)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1104: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Daily Physical Activities
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	89 (68.5%)	32 (49.2%)
Mean (SD)	19.04 (53.46)	-1.41 (26.68)
Median	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
Min, Max	-66.7, 300.0	-66.7, 66.7
Return Rate (%)	69%	51%
Number of Subjects in Risk	101	39
Return Rate in Risk (%)	89%	85%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-promis.sas V.03.05 Output file: t-promis-dpa.pdf 31AUG2023:16:01

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Study SRA-MMB-301

Table 2.1102: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Lifting and Carrying Groceries

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Lifting and Carrying Groceries Item Score		
Baseline		
n (%)	129 (99.2%)	64 (98.5%)
Mean (SD)	2.77 (1.13)	3.14 (1.39)
Median	3.00	3.00
Q1, Q3	2.00, 4.00	2.00, 4.00
Min, Max	1.0, 5.0	1.0, 5.0
Return Rate (%)	99%	98%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	99%	98%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1102: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Lifting and Carrying Groceries
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 2		
n (%)	122 (93.8%)	53 (81.5%)
Mean (SD)	2.97 (1.21)	3.02 (1.20)
Median	3.00	3.00
Q1, Q3	2.00, 4.00	2.00, 4.00
Min, Max	1.0, 5.0	1.0, 5.0
Change from Baseline		
n (%)	121 (93.1%)	52 (80.0%)
Mean (SD)	0.27 (0.96)	-0.08 (0.99)
Median	0.00	0.00
Q1, Q3	0.00, 1.00	-1.00, 0.00
Min, Max	-2.0, 4.0	-2.0, 3.0
Least Squares Mean (SE) [1]	0.24 (0.09)	-0.13 (0.13)
95% CI [1]	0.06, 0.42	-0.39, 0.14
Least Squares Mean Difference (SE) [1]	0.36 (0.16)	
95% CI [1]	0.06, 0.67	
p-value [2]	0.020	
Corrected Hedges' g (95% CI)	0.370 (0.043, 0.697)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Study SRA-MMB-301

Table 2.1102: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Lifting and Carrying Groceries

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	121 (93.1%)	52 (80.0%)
Mean (SD)	18.82 (56.53)	9.49 (58.70)
Median	0.00	0.00
Q1, Q3	0.00, 33.33	-20.00, 0.00
Min, Max	-50.0, 400.0	-66.7, 300.0
Return Rate (%)	94%	82%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	94%	82%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1102: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Lifting and Carrying Groceries
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 4		
n (%)	120 (92.3%)	53 (81.5%)
Mean (SD)	3.12 (1.21)	3.19 (1.23)
Median	3.00	3.00
Q1, Q3	2.00, 4.00	2.00, 4.00
Min, Max	1.0, 5.0	1.0, 5.0
Change from Baseline		
n (%)	119 (91.5%)	52 (80.0%)
Mean (SD)	0.37 (0.97)	-0.06 (0.92)
Median	0.00	0.00
Q1, Q3	0.00, 1.00	-1.00, 0.00
Min, Max	-1.0, 4.0	-2.0, 3.0
Least Squares Mean (SE) [1]	0.33 (0.09)	-0.07 (0.13)
95% CI [1]	0.15, 0.50	-0.33, 0.19
Least Squares Mean Difference (SE) [1]	0.40 (0.15)	
95% CI [1]	0.10, 0.70	
p-value [2]	0.010	
Corrected Hedges' g (95% CI)	0.413 (0.084, 0.742)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.1102: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Lifting and Carrying Groceries
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	119 (91.5%)	52 (80.0%)
Mean (SD)	23.31 (62.89)	7.18 (52.61)
Median	0.00	0.00
Q1, Q3	0.00, 50.00	-20.00, 0.00
Min, Max	-50.0, 400.0	-50.0, 300.0
Return Rate (%)	92%	82%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	92%	82%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

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Study SRA-MMB-301

Table 2.1102: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Lifting and Carrying Groceries

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 8		
n (%)	119 (91.5%)	49 (75.4%)
Mean (SD)	3.16 (1.23)	3.10 (1.23)
Median	3.00	3.00
Q1, Q3	2.00, 4.00	2.00, 4.00
Min, Max	1.0, 5.0	1.0, 5.0
Change from Baseline		
n (%)	118 (90.8%)	48 (73.8%)
Mean (SD)	0.39 (1.11)	-0.23 (0.72)
Median	0.00	0.00
Q1, Q3	0.00, 1.00	-1.00, 0.00
Min, Max	-3.0, 4.0	-2.0, 2.0
Least Squares Mean (SE) [1]	0.35 (0.10)	-0.16 (0.14)
95% CI [1]	0.16, 0.54	-0.45, 0.12
Least Squares Mean Difference (SE) [1]	0.52 (0.17)	
95% CI [1]	0.18, 0.85	
p-value [2]	0.002	
Corrected Hedges' g (95% CI)	0.500 (0.160, 0.840)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1102: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Lifting and Carrying Groceries
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	118 (90.8%)	48 (73.8%)
Mean (SD)	26.91 (66.57)	-2.43 (33.61)
Median	0.00	0.00
Q1, Q3	0.00, 50.00	-20.00, 0.00
Min, Max	-75.0, 400.0	-50.0, 100.0
Return Rate (%)	92%	75%
Number of Subjects in Risk	129	63
Return Rate in Risk (%)	92%	78%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1102: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Lifting and Carrying Groceries
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 12		
n (%)	103 (79.2%)	46 (70.8%)
Mean (SD)	3.23 (1.16)	3.54 (1.28)
Median	3.00	3.00
Q1, Q3	2.00, 4.00	3.00, 5.00
Min, Max	1.0, 5.0	1.0, 5.0
Change from Baseline		
n (%)	102 (78.5%)	45 (69.2%)
Mean (SD)	0.49 (1.13)	0.04 (0.80)
Median	0.00	0.00
Q1, Q3	0.00, 1.00	0.00, 0.00
Min, Max	-2.0, 4.0	-1.0, 2.0
Least Squares Mean (SE) [1]	0.40 (0.10)	0.08 (0.15)
95% CI [1]	0.20, 0.60	-0.21, 0.38
Least Squares Mean Difference (SE) [1]	0.32 (0.18)	
95% CI [1]	-0.03, 0.67	
p-value [2]	0.077	
Corrected Hedges' g (95% CI)	0.307 (-0.045, 0.660)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

GSK Oncology

Study SRA-MMB-301

Table 2.1102: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Lifting and Carrying Groceries

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	102 (78.5%)	45 (69.2%)
Mean (SD)	33.02 (68.61)	5.89 (31.48)
Median	0.00	0.00
Q1, Q3	0.00, 66.67	0.00, 0.00
Min, Max	-50.0, 400.0	-33.3, 100.0
Return Rate (%)	79%	71%
Number of Subjects in Risk	121	52
Return Rate in Risk (%)	85%	88%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1102: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Lifting and Carrying Groceries
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 16		
n (%)	102 (78.5%)	36 (55.4%)
Mean (SD)	3.18 (1.21)	3.25 (1.23)
Median	3.00	3.00
Q1, Q3	2.00, 4.00	2.00, 4.00
Min, Max	1.0, 5.0	1.0, 5.0
Change from Baseline		
n (%)	101 (77.7%)	35 (53.8%)
Mean (SD)	0.42 (1.11)	-0.23 (0.94)
Median	0.00	0.00
Q1, Q3	0.00, 1.00	-1.00, 0.00
Min, Max	-2.0, 4.0	-2.0, 2.0
Least Squares Mean (SE) [1]	0.25 (0.10)	-0.20 (0.16)
95% CI [1]	0.05, 0.46	-0.52, 0.11
Least Squares Mean Difference (SE) [1]	0.45 (0.19)	
95% CI [1]	0.09, 0.82	
p-value [2]	0.016	
Corrected Hedges' g (95% CI)	0.447 (0.059, 0.835)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.1102: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Lifting and Carrying Groceries
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	101 (77.7%)	35 (53.8%)
Mean (SD)	29.49 (72.29)	-1.86 (32.69)
Median	0.00	0.00
Q1, Q3	0.00, 50.00	-20.00, 0.00
Min, Max	-66.7, 400.0	-50.0, 100.0
Return Rate (%)	78%	55%
Number of Subjects in Risk	113	48
Return Rate in Risk (%)	90%	75%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1102: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Lifting and Carrying Groceries
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 20		
n (%)	98 (75.4%)	33 (50.8%)
Mean (SD)	3.17 (1.19)	3.36 (1.22)
Median	3.00	4.00
Q1, Q3	2.00, 4.00	3.00, 4.00
Min, Max	1.0, 5.0	1.0, 5.0
Change from Baseline		
n (%)	97 (74.6%)	33 (50.8%)
Mean (SD)	0.43 (1.15)	-0.09 (0.88)
Median	0.00	0.00
Q1, Q3	0.00, 1.00	0.00, 0.00
Min, Max	-2.0, 4.0	-2.0, 2.0
Least Squares Mean (SE) [1]	0.29 (0.10)	-0.12 (0.16)
95% CI [1]	0.08, 0.49	-0.45, 0.20
Least Squares Mean Difference (SE) [1]	0.41 (0.19)	
95% CI [1]	0.03, 0.79	
p-value [2]	0.034	
Corrected Hedges' g (95% CI)	0.403 (0.005, 0.801)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.1102: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Lifting and Carrying Groceries
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	97 (74.6%)	33 (50.8%)
Mean (SD)	31.39 (70.23)	0.30 (25.23)
Median	0.00	0.00
Q1, Q3	0.00, 50.00	0.00, 0.00
Min, Max	-66.7, 400.0	-40.0, 66.7
Return Rate (%)	75%	51%
Number of Subjects in Risk	107	41
Return Rate in Risk (%)	92%	80%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1102: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Lifting and Carrying Groceries
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 24		
n (%)	90 (69.2%)	33 (50.8%)
Mean (SD)	3.22 (1.30)	3.55 (1.20)
Median	3.00	4.00
Q1, Q3	2.00, 4.00	3.00, 4.00
Min, Max	1.0, 5.0	1.0, 5.0
Change from Baseline		
n (%)	89 (68.5%)	32 (49.2%)
Mean (SD)	0.52 (1.31)	0.13 (0.91)
Median	0.00	0.00
Q1, Q3	0.00, 1.00	-0.50, 1.00
Min, Max	-3.0, 4.0	-1.0, 2.0
Least Squares Mean (SE) [1]	0.31 (0.12)	0.04 (0.19)
95% CI [1]	0.07, 0.55	-0.34, 0.42
Least Squares Mean Difference (SE) [1]	0.27 (0.22)	
95% CI [1]	-0.17, 0.71	
p-value [2]	0.23	
Corrected Hedges' g (95% CI)	0.238 (-0.168, 0.643)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Study SRA-MMB-301

Table 2.1102: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Lifting and Carrying Groceries

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	89 (68.5%)	32 (49.2%)
Mean (SD)	36.59 (87.85)	7.24 (31.40)
Median	0.00	0.00
Q1, Q3	0.00, 50.00	-10.00, 29.17
Min, Max	-75.0, 400.0	-33.3, 100.0
Return Rate (%)	69%	51%
Number of Subjects in Risk	101	39
Return Rate in Risk (%)	89%	85%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

GSK Oncology

Study SRA-MMB-301

Table 2.1103: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Short Walk

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Short Walk Item Score		
Baseline		
n (%)	129 (99.2%)	64 (98.5%)
Mean (SD)	3.36 (1.25)	3.55 (1.25)
Median	3.00	4.00
Q1, Q3	2.00, 4.00	3.00, 5.00
Min, Max	1.0, 5.0	1.0, 5.0
Return Rate (%)	99%	98%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	99%	98%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1103: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Short Walk
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 2		
n (%)	122 (93.8%)	53 (81.5%)
Mean (SD)	3.43 (1.30)	3.21 (1.38)
Median	3.00	3.00
Q1, Q3	2.00, 5.00	2.00, 4.00
Min, Max	1.0, 5.0	1.0, 5.0
Change from Baseline		
n (%)	121 (93.1%)	52 (80.0%)
Mean (SD)	0.12 (1.11)	-0.29 (1.00)
Median	0.00	0.00
Q1, Q3	0.00, 1.00	-1.00, 0.00
Min, Max	-3.0, 3.0	-3.0, 2.0
Least Squares Mean (SE) [1]	0.07 (0.10)	-0.34 (0.14)
95% CI [1]	-0.12, 0.27	-0.63, -0.06
Least Squares Mean Difference (SE) [1]	0.42 (0.17)	
95% CI [1]	0.09, 0.75	
p-value [2]	0.014	
Corrected Hedges' g (95% CI)	0.394 (0.067, 0.722)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.1103: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Short Walk
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	121 (93.1%)	52 (80.0%)
Mean (SD)	11.20 (49.49)	-4.65 (35.24)
Median	0.00	0.00
Q1, Q3	0.00, 25.00	-25.00, 0.00
Min, Max	-66.7, 300.0	-66.7, 100.0
Return Rate (%)	94%	82%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	94%	82%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-promis.sas V.03.05 Output file: t-promis-sw.pdf 31AUG2023:16:01

Table 2.1103: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Short Walk
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 4		
n (%)	120 (92.3%)	53 (81.5%)
Mean (SD)	3.62 (1.27)	3.49 (1.28)
Median	4.00	4.00
Q1, Q3	3.00, 5.00	2.00, 5.00
Min, Max	1.0, 5.0	1.0, 5.0
Change from Baseline		
n (%)	119 (91.5%)	52 (80.0%)
Mean (SD)	0.29 (1.02)	-0.08 (0.88)
Median	0.00	0.00
Q1, Q3	0.00, 1.00	0.00, 0.00
Min, Max	-2.0, 4.0	-3.0, 1.0
Least Squares Mean (SE) [1]	0.24 (0.09)	-0.12 (0.13)
95% CI [1]	0.06, 0.42	-0.38, 0.15
Least Squares Mean Difference (SE) [1]	0.35 (0.16)	
95% CI [1]	0.04, 0.66	
p-value [2]	0.025	
Corrected Hedges' g (95% CI)	0.358 (0.030, 0.686)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.1103: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Short Walk
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	119 (91.5%)	52 (80.0%)
Mean (SD)	16.82 (52.59)	2.53 (34.07)
Median	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
Min, Max	-66.7, 400.0	-66.7, 100.0
Return Rate (%)	92%	82%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	92%	82%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-promis.sas V.03.05 Output file: t-promis-sw.pdf 31AUG2023:16:01

Table 2.1103: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Short Walk
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 8		
n (%)	119 (91.5%)	49 (75.4%)
Mean (SD)	3.55 (1.31)	3.37 (1.36)
Median	4.00	3.00
Q1, Q3	3.00, 5.00	2.00, 5.00
Min, Max	1.0, 5.0	1.0, 5.0
Change from Baseline		
n (%)	118 (90.8%)	48 (73.8%)
Mean (SD)	0.18 (1.20)	-0.19 (1.02)
Median	0.00	0.00
Q1, Q3	0.00, 1.00	-1.00, 0.00
Min, Max	-4.0, 4.0	-2.0, 3.0
Least Squares Mean (SE) [1]	0.15 (0.11)	-0.30 (0.16)
95% CI [1]	-0.06, 0.37	-0.62, 0.03
Least Squares Mean Difference (SE) [1]	0.45 (0.19)	
95% CI [1]	0.07, 0.83	
p-value [2]	0.021	
Corrected Hedges' g (95% CI)	0.383 (0.045, 0.721)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.1103: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Short Walk
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	118 (90.8%)	48 (73.8%)
Mean (SD)	13.69 (55.54)	0.83 (53.88)
Median	0.00	0.00
Q1, Q3	0.00, 33.33	-29.17, 0.00
Min, Max	-80.0, 400.0	-66.7, 300.0
Return Rate (%)	92%	75%
Number of Subjects in Risk	129	63
Return Rate in Risk (%)	92%	78%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-promis.sas V.03.05 Output file: t-promis-sw.pdf 31AUG2023:16:01

Table 2.1103: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Short Walk
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 12		
n (%)	103 (79.2%)	46 (70.8%)
Mean (SD)	3.63 (1.31)	3.78 (1.28)
Median	4.00	4.00
Q1, Q3	2.00, 5.00	3.00, 5.00
Min, Max	1.0, 5.0	1.0, 5.0
Change from Baseline		
n (%)	102 (78.5%)	45 (69.2%)
Mean (SD)	0.27 (1.10)	0.09 (1.02)
Median	0.00	0.00
Q1, Q3	0.00, 1.00	0.00, 1.00
Min, Max	-2.0, 3.0	-2.0, 2.0
Least Squares Mean (SE) [1]	0.20 (0.10)	0.02 (0.15)
95% CI [1]	0.00, 0.40	-0.28, 0.32
Least Squares Mean Difference (SE) [1]	0.18 (0.18)	
95% CI [1]	-0.17, 0.54	
p-value [2]	0.31	
Corrected Hedges' g (95% CI)	0.176 (-0.175, 0.527)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.1103: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Short Walk
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	102 (78.5%)	45 (69.2%)
Mean (SD)	16.05 (48.59)	8.26 (44.18)
Median	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 25.00
Min, Max	-50.0, 200.0	-66.7, 200.0
Return Rate (%)	79%	71%
Number of Subjects in Risk	121	52
Return Rate in Risk (%)	85%	88%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-promis.sas V.03.05 Output file: t-promis-sw.pdf 31AUG2023:16:01

Table 2.1103: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Short Walk
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 16		
n (%)	102 (78.5%)	36 (55.4%)
Mean (SD)	3.58 (1.32)	3.56 (1.32)
Median	4.00	3.00
Q1, Q3	2.00, 5.00	3.00, 5.00
Min, Max	1.0, 5.0	1.0, 5.0
Change from Baseline		
n (%)	101 (77.7%)	35 (53.8%)
Mean (SD)	0.20 (1.12)	-0.17 (1.07)
Median	0.00	0.00
Q1, Q3	0.00, 0.00	-1.00, 1.00
Min, Max	-3.0, 3.0	-2.0, 2.0
Least Squares Mean (SE) [1]	0.10 (0.11)	-0.22 (0.17)
95% CI [1]	-0.11, 0.31	-0.56, 0.11
Least Squares Mean Difference (SE) [1]	0.32 (0.20)	
95% CI [1]	-0.07, 0.72	
p-value [2]	0.10	
Corrected Hedges' g (95% CI)	0.303 (-0.083, 0.690)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.1103: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Short Walk
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	101 (77.7%)	35 (53.8%)
Mean (SD)	12.28 (45.53)	-2.00 (31.44)
Median	0.00	0.00
Q1, Q3	0.00, 0.00	-25.00, 25.00
Min, Max	-60.0, 150.0	-66.7, 66.7
Return Rate (%)	78%	55%
Number of Subjects in Risk	113	48
Return Rate in Risk (%)	90%	75%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1103: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Short Walk
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 20		
n (%)	98 (75.4%)	33 (50.8%)
Mean (SD)	3.50 (1.20)	3.64 (1.19)
Median	3.50	4.00
Q1, Q3	3.00, 5.00	3.00, 5.00
Min, Max	1.0, 5.0	1.0, 5.0
Change from Baseline		
n (%)	97 (74.6%)	33 (50.8%)
Mean (SD)	0.16 (1.02)	-0.03 (0.85)
Median	0.00	0.00
Q1, Q3	0.00, 1.00	-1.00, 0.00
Min, Max	-2.0, 3.0	-1.0, 2.0
Least Squares Mean (SE) [1]	0.07 (0.10)	-0.23 (0.15)
95% CI [1]	-0.12, 0.26	-0.53, 0.08
Least Squares Mean Difference (SE) [1]	0.30 (0.18)	
95% CI [1]	-0.06, 0.65	
p-value [2]	0.099	
Corrected Hedges' g (95% CI)	0.314 (-0.083, 0.711)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.1103: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Short Walk
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	97 (74.6%)	33 (50.8%)
Mean (SD)	12.51 (45.49)	2.98 (30.62)
Median	0.00	0.00
Q1, Q3	0.00, 25.00	-20.00, 0.00
Min, Max	-66.7, 200.0	-33.3, 100.0
Return Rate (%)	75%	51%
Number of Subjects in Risk	107	41
Return Rate in Risk (%)	92%	80%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1103: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Short Walk
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 24		
n (%)	90 (69.2%)	33 (50.8%)
Mean (SD)	3.71 (1.30)	3.82 (1.21)
Median	4.00	4.00
Q1, Q3	3.00, 5.00	3.00, 5.00
Min, Max	1.0, 5.0	1.0, 5.0
Change from Baseline		
n (%)	89 (68.5%)	32 (49.2%)
Mean (SD)	0.38 (1.21)	0.13 (1.04)
Median	0.00	0.00
Q1, Q3	0.00, 1.00	0.00, 1.00
Min, Max	-2.0, 4.0	-2.0, 2.0
Least Squares Mean (SE) [1]	0.24 (0.12)	0.01 (0.19)
95% CI [1]	0.01, 0.47	-0.35, 0.38
Least Squares Mean Difference (SE) [1]	0.22 (0.22)	
95% CI [1]	-0.20, 0.65	
p-value [2]	0.30	
Corrected Hedges' g (95% CI)	0.205 (-0.200, 0.610)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.1103: Physical Function (PROMIS) Individual Item Score Change From Baseline Over the 24-Week Randomized Treatment Period - Short Walk
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	89 (68.5%)	32 (49.2%)
Mean (SD)	22.96 (63.97)	6.56 (32.35)
Median	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 25.00
Min, Max	-66.7, 400.0	-50.0, 66.7
Return Rate (%)	69%	51%
Number of Subjects in Risk	101	39
Return Rate in Risk (%)	89%	85%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Table 2.1001: Physical Function (PROMIS) 10b Total Score Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
10b Total Score		
Baseline		
n (%)	129 (99.2%)	64 (98.5%)
Mean (SD)	32.49 (9.55)	34.38 (10.45)
Median	33.00	37.00
Q1, Q3	26.00, 41.00	28.50, 43.00
Min, Max	10.0, 49.0	10.0, 49.0
Return Rate (%)	99%	98%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	99%	98%

PROMIS Short Form 10b consists of 10 questions, where the total score is the sum of all the scores for each of these questions.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1001: Physical Function (PROMIS) 10b Total Score Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 2		
n (%)	122 (93.8%)	53 (81.5%)
Mean (SD)	32.32 (9.58)	32.91 (10.51)
Median	33.50	35.00
Q1, Q3	25.00, 40.00	24.00, 42.00
Min, Max	10.0, 49.0	12.0, 49.0
Change from Baseline		
n (%)	121 (93.1%)	52 (80.0%)
Mean (SD)	0.37 (6.60)	-1.67 (5.61)
Median	0.00	-2.00
Q1, Q3	-3.00, 4.00	-4.50, 0.00
Min, Max	-24.0, 18.0	-16.0, 16.0
Least Squares Mean (SE) [1]	0.37 (0.58)	-1.39 (0.86)
95% CI [1]	-0.78, 1.53	-3.09, 0.30
Least Squares Mean Difference (SE) [1]	1.77 (1.01)	
95% CI [1]	-0.22, 3.76	
p-value [2]	0.081	
Corrected Hedges' g (95% CI)	0.277 (-0.050, 0.603)	

PROMIS Short Form 10b consists of 10 questions, where the total score is the sum of all the scores for each of these questions.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1001: Physical Function (PROMIS) 10b Total Score Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	121 (93.1%)	52 (80.0%)
Mean (SD)	3.83 (24.47)	-4.37 (19.19)
Median	0.00	-5.06
Q1, Q3	-9.76, 12.12	-12.07, 0.00
Min, Max	-63.2, 107.1	-42.1, 59.3
Return Rate (%)	94%	82%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	94%	82%

PROMIS Short Form 10b consists of 10 questions, where the total score is the sum of all the scores for each of these questions.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1001: Physical Function (PROMIS) 10b Total Score Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 4		
n (%)	120 (92.3%)	53 (81.5%)
Mean (SD)	32.63 (9.46)	34.00 (10.33)
Median	34.00	37.00
Q1, Q3	26.50, 40.50	26.00, 42.00
Min, Max	11.0, 49.0	13.0, 50.0
Change from Baseline		
n (%)	119 (91.5%)	52 (80.0%)
Mean (SD)	0.26 (6.72)	-0.92 (5.19)
Median	0.00	-1.00
Q1, Q3	-3.00, 4.00	-4.50, 1.00
Min, Max	-15.0, 20.0	-20.0, 10.0
Least Squares Mean (SE) [1]	0.23 (0.57)	-0.94 (0.84)
95% CI [1]	-0.90, 1.37	-2.59, 0.71
Least Squares Mean Difference (SE) [1]	1.18 (0.98)	
95% CI [1]	-0.76, 3.12	
p-value [2]	0.23	
Corrected Hedges' g (95% CI)	0.189 (-0.137, 0.516)	

PROMIS Short Form 10b consists of 10 questions, where the total score is the sum of all the scores for each of these questions.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1001: Physical Function (PROMIS) 10b Total Score Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	119 (91.5%)	52 (80.0%)
Mean (SD)	3.78 (25.38)	-1.86 (15.82)
Median	0.00	-2.27
Q1, Q3	-10.34, 12.50	-13.33, 4.43
Min, Max	-46.2, 121.4	-52.6, 27.8
Return Rate (%)	92%	82%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	92%	82%

PROMIS Short Form 10b consists of 10 questions, where the total score is the sum of all the scores for each of these questions.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1001: Physical Function (PROMIS) 10b Total Score Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 8		
n (%)	119 (91.5%)	49 (75.4%)
Mean (SD)	33.04 (9.62)	33.20 (10.41)
Median	34.00	34.00
Q1, Q3	26.00, 41.00	22.00, 41.00
Min, Max	11.0, 49.0	13.0, 50.0
Change from Baseline		
n (%)	118 (90.8%)	48 (73.8%)
Mean (SD)	0.31 (7.39)	-2.23 (6.20)
Median	0.00	-2.00
Q1, Q3	-3.00, 5.00	-5.00, 0.50
Min, Max	-21.0, 22.0	-19.0, 16.0
Least Squares Mean (SE) [1]	0.35 (0.66)	-2.09 (0.98)
95% CI [1]	-0.95, 1.65	-4.01, -0.17
Least Squares Mean Difference (SE) [1]	2.44 (1.15)	
95% CI [1]	0.17, 4.71	
p-value [2]	0.035	
Corrected Hedges' g (95% CI)	0.345 (0.007, 0.683)	

PROMIS Short Form 10b consists of 10 questions, where the total score is the sum of all the scores for each of these questions.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1001: Physical Function (PROMIS) 10b Total Score Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	118 (90.8%)	48 (73.8%)
Mean (SD)	4.18 (27.99)	-5.35 (22.25)
Median	0.00	-4.77
Q1, Q3	-8.89, 14.71	-18.75, 1.04
Min, Max	-55.3, 157.1	-50.0, 88.9
Return Rate (%)	92%	75%
Number of Subjects in Risk	129	63
Return Rate in Risk (%)	92%	78%

PROMIS Short Form 10b consists of 10 questions, where the total score is the sum of all the scores for each of these questions.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1001: Physical Function (PROMIS) 10b Total Score Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 12		
n (%)	103 (79.2%)	46 (70.8%)
Mean (SD)	34.92 (9.92)	37.13 (9.18)
Median	37.00	38.00
Q1, Q3	29.00, 43.00	30.00, 44.00
Min, Max	12.0, 49.0	14.0, 50.0
Change from Baseline		
n (%)	102 (78.5%)	45 (69.2%)
Mean (SD)	2.21 (7.32)	0.02 (5.10)
Median	1.50	-1.00
Q1, Q3	-2.00, 5.00	-2.00, 3.00
Min, Max	-14.0, 30.0	-17.0, 13.0
Least Squares Mean (SE) [1]	1.86 (0.64)	0.24 (0.94)
95% CI [1]	0.60, 3.12	-1.61, 2.10
Least Squares Mean Difference (SE) [1]	1.62 (1.11)	
95% CI [1]	-0.58, 3.81	
p-value [2]	0.15	
Corrected Hedges' g (95% CI)	0.251 (-0.101, 0.603)	

PROMIS Short Form 10b consists of 10 questions, where the total score is the sum of all the scores for each of these questions.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1001: Physical Function (PROMIS) 10b Total Score Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	102 (78.5%)	45 (69.2%)
Mean (SD)	10.36 (32.04)	0.86 (15.08)
Median	4.49	-2.08
Q1, Q3	-8.51, 21.05	-6.67, 7.50
Min, Max	-53.8, 214.3	-44.7, 42.9
Return Rate (%)	79%	71%
Number of Subjects in Risk	121	52
Return Rate in Risk (%)	85%	88%

PROMIS Short Form 10b consists of 10 questions, where the total score is the sum of all the scores for each of these questions.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1001: Physical Function (PROMIS) 10b Total Score Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 16		
n (%)	102 (78.5%)	36 (55.4%)
Mean (SD)	33.79 (9.69)	35.11 (9.47)
Median	35.00	35.50
Q1, Q3	27.00, 42.00	28.00, 43.50
Min, Max	13.0, 49.0	15.0, 49.0
Change from Baseline		
n (%)	101 (77.7%)	35 (53.8%)
Mean (SD)	0.82 (7.91)	-2.91 (6.93)
Median	0.00	-2.00
Q1, Q3	-4.00, 5.00	-6.00, 1.00
Min, Max	-18.0, 30.0	-18.0, 13.0
Least Squares Mean (SE) [1]	0.15 (0.72)	-2.67 (1.12)
95% CI [1]	-1.28, 1.58	-4.88, -0.45
Least Squares Mean Difference (SE) [1]	2.81 (1.31)	
95% CI [1]	0.23, 5.40	
p-value [2]	0.033	
Corrected Hedges' g (95% CI)	0.394 (0.006, 0.781)	

PROMIS Short Form 10b consists of 10 questions, where the total score is the sum of all the scores for each of these questions.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.1001: Physical Function (PROMIS) 10b Total Score Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	101 (77.7%)	35 (53.8%)
Mean (SD)	6.53 (33.74)	-6.63 (18.72)
Median	0.00	-6.25
Q1, Q3	-11.36, 15.79	-13.33, 2.08
Min, Max	-41.9, 214.3	-48.6, 36.1
Return Rate (%)	78%	55%
Number of Subjects in Risk	113	48
Return Rate in Risk (%)	90%	75%

PROMIS Short Form 10b consists of 10 questions, where the total score is the sum of all the scores for each of these questions.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.1001: Physical Function (PROMIS) 10b Total Score Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 20		
n (%)	98 (75.4%)	33 (50.8%)
Mean (SD)	33.10 (9.99)	35.27 (8.92)
Median	34.00	37.00
Q1, Q3	26.00, 41.00	28.00, 41.00
Min, Max	11.0, 50.0	13.0, 50.0
Change from Baseline		
n (%)	97 (74.6%)	33 (50.8%)
Mean (SD)	0.32 (8.28)	-2.24 (6.83)
Median	0.00	-2.00
Q1, Q3	-5.00, 6.00	-5.00, 1.00
Min, Max	-18.0, 35.0	-20.0, 13.0
Least Squares Mean (SE) [1]	-0.43 (0.75)	-2.91 (1.17)
95% CI [1]	-1.91, 1.05	-5.22, -0.60
Least Squares Mean Difference (SE) [1]	2.49 (1.37)	
95% CI [1]	-0.21, 5.19	
p-value [2]	0.071	
Corrected Hedges' g (95% CI)	0.342 (-0.055, 0.739)	

PROMIS Short Form 10b consists of 10 questions, where the total score is the sum of all the scores for each of these questions.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1001: Physical Function (PROMIS) 10b Total Score Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	97 (74.6%)	33 (50.8%)
Mean (SD)	4.40 (34.82)	-5.18 (17.64)
Median	0.00	-5.13
Q1, Q3	-15.56, 19.23	-16.13, 3.33
Min, Max	-47.4, 250.0	-54.1, 36.1
Return Rate (%)	75%	51%
Number of Subjects in Risk	107	41
Return Rate in Risk (%)	92%	80%

PROMIS Short Form 10b consists of 10 questions, where the total score is the sum of all the scores for each of these questions.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1001: Physical Function (PROMIS) 10b Total Score Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 24		
n (%)	90 (69.2%)	33 (50.8%)
Mean (SD)	34.77 (10.00)	37.27 (8.86)
Median	37.00	39.00
Q1, Q3	28.00, 43.00	31.00, 44.00
Min, Max	13.0, 50.0	13.0, 49.0
Change from Baseline		
n (%)	89 (68.5%)	32 (49.2%)
Mean (SD)	1.94 (8.74)	0.22 (5.79)
Median	1.00	1.00
Q1, Q3	-4.00, 7.00	-2.00, 2.50
Min, Max	-22.0, 35.0	-16.0, 13.0
Least Squares Mean (SE) [1]	1.19 (0.77)	-0.11 (1.21)
95% CI [1]	-0.33, 2.72	-2.51, 2.28
Least Squares Mean Difference (SE) [1]	1.31 (1.42)	
95% CI [1]	-1.49, 4.11	
p-value [2]	0.36	
Corrected Hedges' g (95% CI)	0.181 (-0.223, 0.586)	

PROMIS Short Form 10b consists of 10 questions, where the total score is the sum of all the scores for each of these questions.
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

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Table 2.1001: Physical Function (PROMIS) 10b Total Score Change From Baseline Over the 24-Week Randomized Treatment Period

Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	89 (68.5%)	32 (49.2%)
Mean (SD)	10.59 (38.85)	1.51 (16.10)
Median	4.35	2.31
Q1, Q3	-12.12, 26.32	-5.40, 7.20
Min, Max	-61.1, 250.0	-42.1, 36.1
Return Rate (%)	69%	51%
Number of Subjects in Risk	101	39
Return Rate in Risk (%)	89%	85%

PROMIS Short Form 10b consists of 10 questions, where the total score is the sum of all the scores for each of these questions.

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).

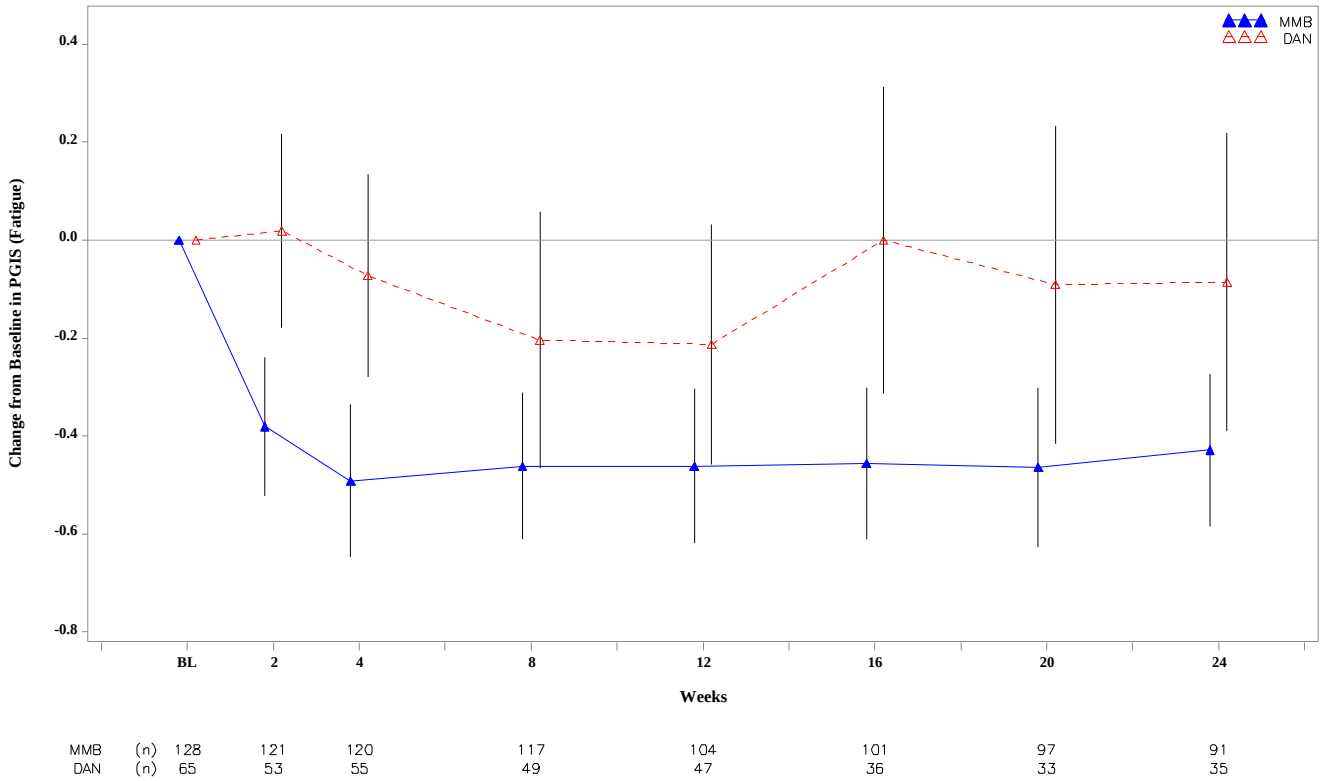
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

3.5 PGIS

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Figure 2.0802: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Fatigue (PGIS)
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

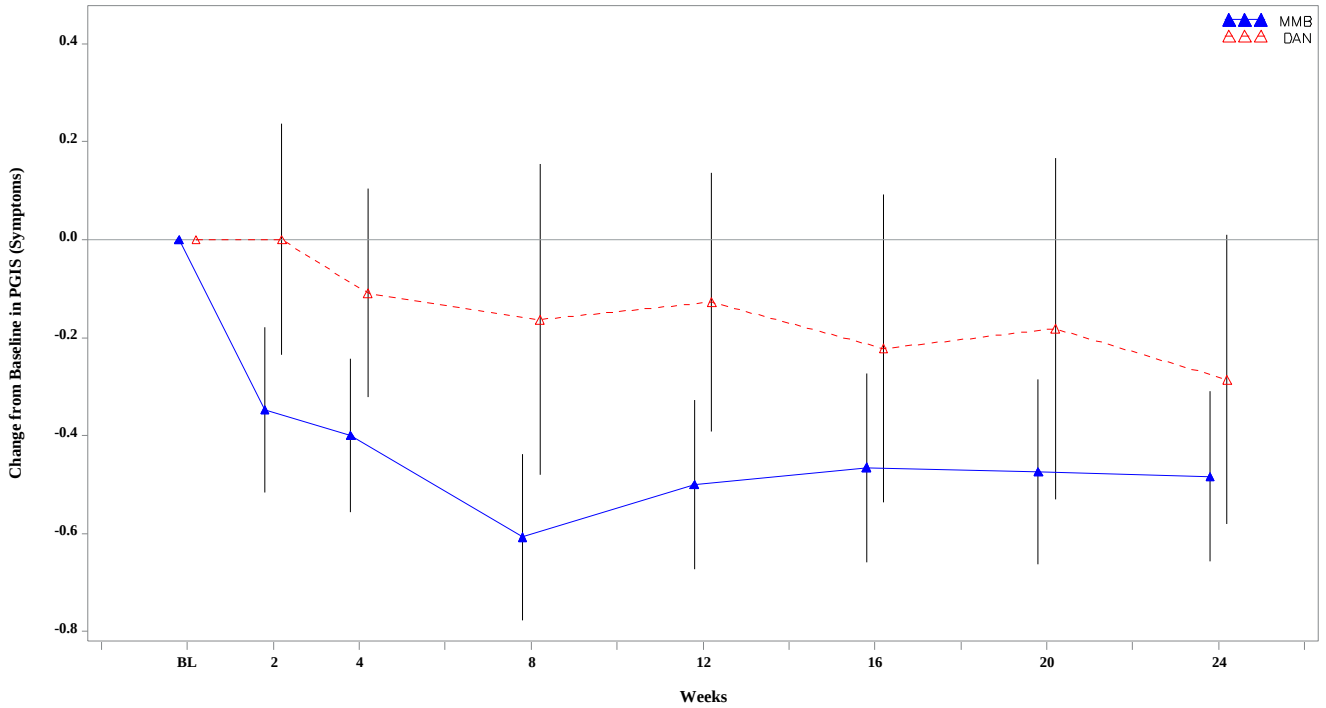


		BL	2	4	8	12	16	20	24
MMB	(n)	128	121	120	117	104	101	97	91
DAN	(n)	65	53	55	49	47	36	33	35

PGIS = Patient Global Impression of Severity

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-pgis-chg-gba.sas V.03.05 Output file: g-pgis-chg-fat-gba.pdf 31AUG2023:15:27

Figure 2.0801: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Symptoms (PGIS)
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set



		BL	2	4	8	12	16	20	24
MMB	(n)	128	121	120	117	104	101	97	91
DAN	(n)	65	53	55	49	47	36	33	35

PGIS = Patient Global Impression of Severity

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-pgis-chg-gba.sas V.03.05 Output file: g-pgis-chg-sym-gba.pdf 31AUG2023:15:27

Table 2.1402: Analysis of Patient Global Impression of Severity of Fatigue Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Baseline		
n (%)	128 (98.5%)	65 (100.0%)
Mean (SD)	3.27 (0.71)	3.05 (0.72)
Median	3.00	3.00
Q1, Q3	3.00, 4.00	3.00, 3.00
Min, Max	1.0, 4.0	1.0, 4.0
Return Rate (%)	98%	100%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	98%	100%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-pgis-mmrm.sas V.03.05 Output file: t-pgis-mmrm-fat.pdf 31AUG2023:16:01

Table 2.1402: Analysis of Patient Global Impression of Severity of Fatigue Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 2		
n (%)	123 (94.6%)	53 (81.5%)
Mean (SD)	2.93 (0.75)	3.02 (0.75)
Median	3.00	3.00
Q1, Q3	2.00, 3.00	2.00, 4.00
Min, Max	1.0, 4.0	2.0, 4.0
Change from Baseline		
n (%)	121 (93.1%)	53 (81.5%)
Mean (SD)	-0.38 (0.79)	0.02 (0.72)
Median	0.00	0.00
Q1, Q3	-1.00, 0.00	0.00, 0.00
Min, Max	-3.0, 1.0	-2.0, 2.0
Least Squares Mean (SE) [1]	-0.39 (0.07)	-0.06 (0.11)
95% CI [1]	-0.53, -0.24	-0.26, 0.15
Least Squares Mean Difference (SE) [1]	-0.33 (0.12)	
95% CI [1]	-0.57, -0.08	
p-value [2]	0.009	
Corrected Hedges' g (95% CI)	-0.414 (-0.740, -0.089)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-pgis-mmrm.sas V.03.05 Output file: t-pgis-mmrm-fat.pdf 31AUG2023:16:01

Table 2.1402: Analysis of Patient Global Impression of Severity of Fatigue Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	121 (93.1%)	53 (81.5%)
Mean (SD)	-8.61 (26.85)	6.76 (43.64)
Median	0.00	0.00
Q1, Q3	-25.00, 0.00	0.00, 0.00
Min, Max	-75.0, 100.0	-50.0, 200.0
Return Rate (%)	95%	82%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	95%	82%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-pgis-mmrm.sas V.03.05 Output file: t-pgis-mmrm-fat.pdf 31AUG2023:16:01

Table 2.1402: Analysis of Patient Global Impression of Severity of Fatigue Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 4		
n (%)	122 (93.8%)	55 (84.6%)
Mean (SD)	2.77 (0.82)	2.96 (0.77)
Median	3.00	3.00
Q1, Q3	2.00, 3.00	2.00, 4.00
Min, Max	1.0, 4.0	1.0, 4.0
Change from Baseline		
n (%)	120 (92.3%)	55 (84.6%)
Mean (SD)	-0.49 (0.86)	-0.07 (0.77)
Median	0.00	0.00
Q1, Q3	-1.00, 0.00	0.00, 0.00
Min, Max	-3.0, 1.0	-2.0, 2.0
Least Squares Mean (SE) [1]	-0.50 (0.08)	-0.07 (0.11)
95% CI [1]	-0.66, -0.35	-0.29, 0.15
Least Squares Mean Difference (SE) [1]	-0.43 (0.13)	
95% CI [1]	-0.70, -0.17	
p-value [2]	0.001	
Corrected Hedges' g (95% CI)	-0.512 (-0.835, -0.188)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-pgis-mmrm.sas V.03.05 Output file: t-pgis-mmrm-fat.pdf 31AUG2023:16:01

Table 2.1402: Analysis of Patient Global Impression of Severity of Fatigue Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	120 (92.3%)	55 (84.6%)
Mean (SD)	-12.57 (27.78)	1.82 (37.60)
Median	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
Min, Max	-75.0, 100.0	-66.7, 200.0
Return Rate (%)	94%	85%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	94%	85%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-pgis-mmrm.sas V.03.05 Output file: t-pgis-mmrm-fat.pdf 31AUG2023:16:01

Table 2.1402: Analysis of Patient Global Impression of Severity of Fatigue Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 8		
n (%)	119 (91.5%)	49 (75.4%)
Mean (SD)	2.82 (0.80)	2.84 (0.83)
Median	3.00	3.00
Q1, Q3	2.00, 3.00	2.00, 3.00
Min, Max	1.0, 4.0	1.0, 4.0
Change from Baseline		
n (%)	117 (90.0%)	49 (75.4%)
Mean (SD)	-0.46 (0.82)	-0.20 (0.91)
Median	0.00	0.00
Q1, Q3	-1.00, 0.00	-1.00, 0.00
Min, Max	-3.0, 1.0	-3.0, 2.0
Least Squares Mean (SE) [1]	-0.46 (0.08)	-0.15 (0.12)
95% CI [1]	-0.62, -0.31	-0.38, 0.08
Least Squares Mean Difference (SE) [1]	-0.31 (0.14)	
95% CI [1]	-0.59, -0.04	
p-value [2]	0.025	
Corrected Hedges' g (95% CI)	-0.365 (-0.701, -0.030)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-pgis-mmrm.sas V.03.05 Output file: t-pgis-mmrm-fat.pdf 31AUG2023:16:01

Table 2.1402: Analysis of Patient Global Impression of Severity of Fatigue Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	117 (90.0%)	49 (75.4%)
Mean (SD)	-11.68 (27.05)	-2.04 (40.06)
Median	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
Min, Max	-75.0, 100.0	-75.0, 200.0
Return Rate (%)	92%	75%
Number of Subjects in Risk	129	63
Return Rate in Risk (%)	92%	78%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
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Table 2.1402: Analysis of Patient Global Impression of Severity of Fatigue Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 12		
n (%)	105 (80.8%)	47 (72.3%)
Mean (SD)	2.77 (0.79)	2.79 (0.81)
Median	3.00	3.00
Q1, Q3	2.00, 3.00	2.00, 3.00
Min, Max	1.0, 4.0	1.0, 4.0
Change from Baseline		
n (%)	104 (80.0%)	47 (72.3%)
Mean (SD)	-0.46 (0.81)	-0.21 (0.83)
Median	0.00	0.00
Q1, Q3	-1.00, 0.00	-1.00, 0.00
Min, Max	-3.0, 1.0	-3.0, 2.0
Least Squares Mean (SE) [1]	-0.48 (0.08)	-0.21 (0.11)
95% CI [1]	-0.64, -0.32	-0.44, 0.02
Least Squares Mean Difference (SE) [1]	-0.27 (0.14)	
95% CI [1]	-0.54, 0.00	
p-value [2]	0.048	
Corrected Hedges' g (95% CI)	-0.337 (-0.683, 0.010)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-pgis-mmrm.sas V.03.05 Output file: t-pgis-mmrm-fat.pdf 31AUG2023:16:01

Table 2.1402: Analysis of Patient Global Impression of Severity of Fatigue Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	104 (80.0%)	47 (72.3%)
Mean (SD)	-11.54 (27.36)	-2.66 (39.89)
Median	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
Min, Max	-75.0, 100.0	-75.0, 200.0
Return Rate (%)	81%	72%
Number of Subjects in Risk	121	52
Return Rate in Risk (%)	87%	90%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
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Table 2.1402: Analysis of Patient Global Impression of Severity of Fatigue Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 16		
n (%)	102 (78.5%)	36 (55.4%)
Mean (SD)	2.79 (0.78)	2.92 (0.84)
Median	3.00	3.00
Q1, Q3	2.00, 3.00	2.00, 3.50
Min, Max	1.0, 4.0	1.0, 4.0
Change from Baseline		
n (%)	101 (77.7%)	36 (55.4%)
Mean (SD)	-0.46 (0.78)	0.00 (0.93)
Median	0.00	0.00
Q1, Q3	-1.00, 0.00	0.00, 0.00
Min, Max	-2.0, 1.0	-3.0, 2.0
Least Squares Mean (SE) [1]	-0.44 (0.08)	-0.08 (0.12)
95% CI [1]	-0.60, -0.28	-0.32, 0.17
Least Squares Mean Difference (SE) [1]	-0.36 (0.15)	
95% CI [1]	-0.65, -0.08	
p-value [2]	0.013	
Corrected Hedges' g (95% CI)	-0.456 (-0.840, -0.072)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.1402: Analysis of Patient Global Impression of Severity of Fatigue Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	101 (77.7%)	36 (55.4%)
Mean (SD)	-12.05 (22.81)	6.02 (45.50)
Median	0.00	0.00
Q1, Q3	-25.00, 0.00	0.00, 0.00
Min, Max	-66.7, 50.0	-75.0, 200.0
Return Rate (%)	78%	55%
Number of Subjects in Risk	113	48
Return Rate in Risk (%)	90%	75%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-pgis-mmrm.sas V.03.05 Output file: t-pgis-mmrm-fat.pdf 31AUG2023:16:01

Table 2.1402: Analysis of Patient Global Impression of Severity of Fatigue Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 20		
n (%)	98 (75.4%)	33 (50.8%)
Mean (SD)	2.80 (0.69)	2.85 (0.83)
Median	3.00	3.00
Q1, Q3	2.00, 3.00	2.00, 3.00
Min, Max	1.0, 4.0	1.0, 4.0
Change from Baseline		
n (%)	97 (74.6%)	33 (50.8%)
Mean (SD)	-0.46 (0.80)	-0.09 (0.91)
Median	0.00	0.00
Q1, Q3	-1.00, 0.00	-1.00, 0.00
Min, Max	-2.0, 1.0	-2.0, 2.0
Least Squares Mean (SE) [1]	-0.43 (0.08)	-0.11 (0.13)
95% CI [1]	-0.59, -0.27	-0.36, 0.14
Least Squares Mean Difference (SE) [1]	-0.32 (0.15)	
95% CI [1]	-0.61, -0.02	
p-value [2]	0.035	
Corrected Hedges' g (95% CI)	-0.401 (-0.799, -0.003)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1402: Analysis of Patient Global Impression of Severity of Fatigue Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	97 (74.6%)	33 (50.8%)
Mean (SD)	-10.91 (26.69)	2.78 (47.17)
Median	0.00	0.00
Q1, Q3	-33.33, 0.00	-25.00, 0.00
Min, Max	-66.7, 100.0	-66.7, 200.0
Return Rate (%)	75%	51%
Number of Subjects in Risk	107	41
Return Rate in Risk (%)	92%	80%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-pgis-mmrm.sas V.03.05 Output file: t-pgis-mmrm-fat.pdf 31AUG2023:16:01

Table 2.1402: Analysis of Patient Global Impression of Severity of Fatigue Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 24		
n (%)	92 (70.8%)	35 (53.8%)
Mean (SD)	2.85 (0.71)	2.91 (0.78)
Median	3.00	3.00
Q1, Q3	2.00, 3.00	2.00, 3.00
Min, Max	1.0, 4.0	1.0, 4.0
Change from Baseline		
n (%)	91 (70.0%)	35 (53.8%)
Mean (SD)	-0.43 (0.75)	-0.09 (0.89)
Median	0.00	0.00
Q1, Q3	-1.00, 0.00	-1.00, 0.00
Min, Max	-2.0, 1.0	-3.0, 2.0
Least Squares Mean (SE) [1]	-0.38 (0.08)	-0.10 (0.12)
95% CI [1]	-0.54, -0.22	-0.34, 0.15
Least Squares Mean Difference (SE) [1]	-0.29 (0.14)	
95% CI [1]	-0.57, 0.00	
p-value [2]	0.047	
Corrected Hedges' g (95% CI)	-0.376 (-0.769, 0.017)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1402: Analysis of Patient Global Impression of Severity of Fatigue Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	91 (70.0%)	35 (53.8%)
Mean (SD)	-10.53 (25.06)	3.33 (43.55)
Median	0.00	0.00
Q1, Q3	-25.00, 0.00	-25.00, 0.00
Min, Max	-66.7, 100.0	-75.0, 200.0
Return Rate (%)	71%	54%
Number of Subjects in Risk	101	39
Return Rate in Risk (%)	91%	90%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-pgis-mmrm.sas V.03.05 Output file: t-pgis-mmrm-fat.pdf 31AUG2023:16:01

Table 2.1401: Analysis of Patient Global Impression of Severity of Symptoms Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Baseline		
n (%)	128 (98.5%)	65 (100.0%)
Mean (SD)	3.07 (0.72)	2.97 (0.68)
Median	3.00	3.00
Q1, Q3	3.00, 4.00	3.00, 3.00
Min, Max	1.0, 4.0	1.0, 4.0
Return Rate (%)	98%	100%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	98%	100%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-pgis-mmrm.sas V.03.05 Output file: t-pgis-mmrm-sym.pdf 31AUG2023:16:01

Table 2.1401: Analysis of Patient Global Impression of Severity of Symptoms Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 2		
n (%)	123 (94.6%)	53 (81.5%)
Mean (SD)	2.76 (0.81)	2.89 (0.85)
Median	3.00	3.00
Q1, Q3	2.00, 3.00	2.00, 3.00
Min, Max	1.0, 4.0	1.0, 4.0
Change from Baseline		
n (%)	121 (93.1%)	53 (81.5%)
Mean (SD)	-0.35 (0.94)	0.00 (0.85)
Median	0.00	0.00
Q1, Q3	-1.00, 0.00	0.00, 0.00
Min, Max	-3.0, 2.0	-2.0, 2.0
Least Squares Mean (SE) [1]	-0.35 (0.08)	-0.08 (0.12)
95% CI [1]	-0.52, -0.18	-0.32, 0.16
Least Squares Mean Difference (SE) [1]	-0.27 (0.15)	
95% CI [1]	-0.55, 0.02	
p-value [2]	0.067	
Corrected Hedges' g (95% CI)	-0.290 (-0.615, 0.034)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-pgis-mmrm.sas V.03.05 Output file: t-pgis-mmrm-sym.pdf 31AUG2023:16:01

Table 2.1401: Analysis of Patient Global Impression of Severity of Symptoms Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	121 (93.1%)	53 (81.5%)
Mean (SD)	-6.96 (34.25)	4.72 (40.84)
Median	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
Min, Max	-75.0, 100.0	-66.7, 200.0
Return Rate (%)	95%	82%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	95%	82%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-pgis-mmrm.sas V.03.05 Output file: t-pgis-mmrm-sym.pdf 31AUG2023:16:01

Table 2.1401: Analysis of Patient Global Impression of Severity of Symptoms Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 4		
n (%)	122 (93.8%)	55 (84.6%)
Mean (SD)	2.66 (0.73)	2.84 (0.79)
Median	3.00	3.00
Q1, Q3	2.00, 3.00	2.00, 3.00
Min, Max	1.0, 4.0	1.0, 4.0
Change from Baseline		
n (%)	120 (92.3%)	55 (84.6%)
Mean (SD)	-0.40 (0.86)	-0.11 (0.79)
Median	0.00	0.00
Q1, Q3	-1.00, 0.00	-1.00, 0.00
Min, Max	-3.0, 2.0	-2.0, 1.0
Least Squares Mean (SE) [1]	-0.40 (0.08)	-0.10 (0.11)
95% CI [1]	-0.55, -0.24	-0.32, 0.13
Least Squares Mean Difference (SE) [1]	-0.30 (0.13)	
95% CI [1]	-0.57, -0.04	
p-value [2]	0.025	
Corrected Hedges' g (95% CI)	-0.351 (-0.672, -0.030)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-pgis-mmrm.sas V.03.05 Output file: t-pgis-mmrm-sym.pdf 31AUG2023:16:01

Table 2.1401: Analysis of Patient Global Impression of Severity of Symptoms Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	120 (92.3%)	55 (84.6%)
Mean (SD)	-8.47 (34.65)	-0.45 (31.07)
Median	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
Min, Max	-75.0, 200.0	-66.7, 100.0
Return Rate (%)	94%	85%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	94%	85%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-pgis-mmrm.sas V.03.05 Output file: t-pgis-mmrm-sym.pdf 31AUG2023:16:01

Table 2.1401: Analysis of Patient Global Impression of Severity of Symptoms Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 8		
n (%)	119 (91.5%)	49 (75.4%)
Mean (SD)	2.48 (0.76)	2.71 (0.82)
Median	3.00	3.00
Q1, Q3	2.00, 3.00	2.00, 3.00
Min, Max	1.0, 4.0	1.0, 4.0
Change from Baseline		
n (%)	117 (90.0%)	49 (75.4%)
Mean (SD)	-0.61 (0.93)	-0.16 (1.11)
Median	-1.00	0.00
Q1, Q3	-1.00, 0.00	-1.00, 0.00
Min, Max	-3.0, 1.0	-2.0, 3.0
Least Squares Mean (SE) [1]	-0.58 (0.09)	-0.17 (0.13)
95% CI [1]	-0.76, -0.41	-0.43, 0.09
Least Squares Mean Difference (SE) [1]	-0.41 (0.16)	
95% CI [1]	-0.72, -0.10	
p-value [2]	0.009	
Corrected Hedges' g (95% CI)	-0.428 (-0.764, -0.091)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-pgis-mmrm.sas V.03.05 Output file: t-pgis-mmrm-sym.pdf 31AUG2023:16:01

Table 2.1401: Analysis of Patient Global Impression of Severity of Symptoms Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	117 (90.0%)	49 (75.4%)
Mean (SD)	-15.81 (30.63)	4.42 (62.11)
Median	-25.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
Min, Max	-75.0, 100.0	-66.7, 300.0
Return Rate (%)	92%	75%
Number of Subjects in Risk	129	63
Return Rate in Risk (%)	92%	78%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-pgis-mmrm.sas V.03.05 Output file: t-pgis-mmrm-sym.pdf 31AUG2023:16:01

Table 2.1401: Analysis of Patient Global Impression of Severity of Symptoms Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 12		
n (%)	105 (80.8%)	47 (72.3%)
Mean (SD)	2.54 (0.81)	2.70 (0.78)
Median	3.00	3.00
Q1, Q3	2.00, 3.00	2.00, 3.00
Min, Max	1.0, 4.0	1.0, 4.0
Change from Baseline		
n (%)	104 (80.0%)	47 (72.3%)
Mean (SD)	-0.50 (0.89)	-0.13 (0.90)
Median	0.00	0.00
Q1, Q3	-1.00, 0.00	-1.00, 0.00
Min, Max	-2.0, 2.0	-2.0, 2.0
Least Squares Mean (SE) [1]	-0.47 (0.09)	-0.15 (0.12)
95% CI [1]	-0.64, -0.30	-0.40, 0.09
Least Squares Mean Difference (SE) [1]	-0.32 (0.15)	
95% CI [1]	-0.61, -0.03	
p-value [2]	0.031	
Corrected Hedges' g (95% CI)	-0.369 (-0.716, -0.022)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
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Table 2.1401: Analysis of Patient Global Impression of Severity of Symptoms Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	104 (80.0%)	47 (72.3%)
Mean (SD)	-12.74 (32.14)	1.77 (43.68)
Median	0.00	0.00
Q1, Q3	-33.33, 0.00	-25.00, 0.00
Min, Max	-66.7, 100.0	-66.7, 200.0
Return Rate (%)	81%	72%
Number of Subjects in Risk	121	52
Return Rate in Risk (%)	87%	90%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-pgis-mmrm.sas V.03.05 Output file: t-pgis-mmrm-sym.pdf 31AUG2023:16:01

Table 2.1401: Analysis of Patient Global Impression of Severity of Symptoms Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 16		
n (%)	102 (78.5%)	36 (55.4%)
Mean (SD)	2.59 (0.78)	2.61 (0.87)
Median	3.00	3.00
Q1, Q3	2.00, 3.00	2.00, 3.00
Min, Max	1.0, 4.0	1.0, 4.0
Change from Baseline		
n (%)	101 (77.7%)	36 (55.4%)
Mean (SD)	-0.47 (0.98)	-0.22 (0.93)
Median	0.00	0.00
Q1, Q3	-1.00, 0.00	-1.00, 0.50
Min, Max	-3.0, 2.0	-2.0, 1.0
Least Squares Mean (SE) [1]	-0.40 (0.09)	-0.21 (0.14)
95% CI [1]	-0.58, -0.22	-0.49, 0.07
Least Squares Mean Difference (SE) [1]	-0.19 (0.17)	
95% CI [1]	-0.52, 0.14	
p-value [2]	0.25	
Corrected Hedges' g (95% CI)	-0.210 (-0.591, 0.171)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1401: Analysis of Patient Global Impression of Severity of Symptoms Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	101 (77.7%)	36 (55.4%)
Mean (SD)	-10.31 (34.94)	-5.09 (32.01)
Median	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 16.67
Min, Max	-75.0, 100.0	-66.7, 50.0
Return Rate (%)	78%	55%
Number of Subjects in Risk	113	48
Return Rate in Risk (%)	90%	75%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1401: Analysis of Patient Global Impression of Severity of Symptoms Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 20		
n (%)	98 (75.4%)	33 (50.8%)
Mean (SD)	2.57 (0.77)	2.67 (0.82)
Median	3.00	3.00
Q1, Q3	2.00, 3.00	2.00, 3.00
Min, Max	1.0, 4.0	1.0, 4.0
Change from Baseline		
n (%)	97 (74.6%)	33 (50.8%)
Mean (SD)	-0.47 (0.94)	-0.18 (0.98)
Median	0.00	0.00
Q1, Q3	-1.00, 0.00	-1.00, 0.00
Min, Max	-3.0, 1.0	-2.0, 2.0
Least Squares Mean (SE) [1]	-0.42 (0.09)	-0.08 (0.15)
95% CI [1]	-0.60, -0.24	-0.37, 0.21
Least Squares Mean Difference (SE) [1]	-0.34 (0.17)	
95% CI [1]	-0.67, 0.00	
p-value [2]	0.048	
Corrected Hedges' g (95% CI)	-0.377 (-0.775, 0.021)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1401: Analysis of Patient Global Impression of Severity of Symptoms Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	97 (74.6%)	33 (50.8%)
Mean (SD)	-11.77 (31.31)	0.00 (48.90)
Median	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
Min, Max	-75.0, 100.0	-66.7, 200.0
Return Rate (%)	75%	51%
Number of Subjects in Risk	107	41
Return Rate in Risk (%)	92%	80%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1401: Analysis of Patient Global Impression of Severity of Symptoms Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 24		
n (%)	92 (70.8%)	35 (53.8%)
Mean (SD)	2.60 (0.73)	2.63 (0.81)
Median	3.00	3.00
Q1, Q3	2.00, 3.00	2.00, 3.00
Min, Max	1.0, 4.0	1.0, 4.0
Change from Baseline		
n (%)	91 (70.0%)	35 (53.8%)
Mean (SD)	-0.48 (0.83)	-0.29 (0.86)
Median	0.00	0.00
Q1, Q3	-1.00, 0.00	-1.00, 0.00
Min, Max	-2.0, 1.0	-2.0, 2.0
Least Squares Mean (SE) [1]	-0.39 (0.08)	-0.19 (0.13)
95% CI [1]	-0.56, -0.22	-0.44, 0.07
Least Squares Mean Difference (SE) [1]	-0.20 (0.15)	
95% CI [1]	-0.50, 0.10	
p-value [2]	0.19	
Corrected Hedges' g (95% CI)	-0.248 (-0.639, 0.143)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022

Table 2.1401: Analysis of Patient Global Impression of Severity of Symptoms Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	91 (70.0%)	35 (53.8%)
Mean (SD)	-12.36 (30.08)	-5.24 (43.12)
Median	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
Min, Max	-66.7, 100.0	-66.7, 200.0
Return Rate (%)	71%	54%
Number of Subjects in Risk	101	39
Return Rate in Risk (%)	91%	90%

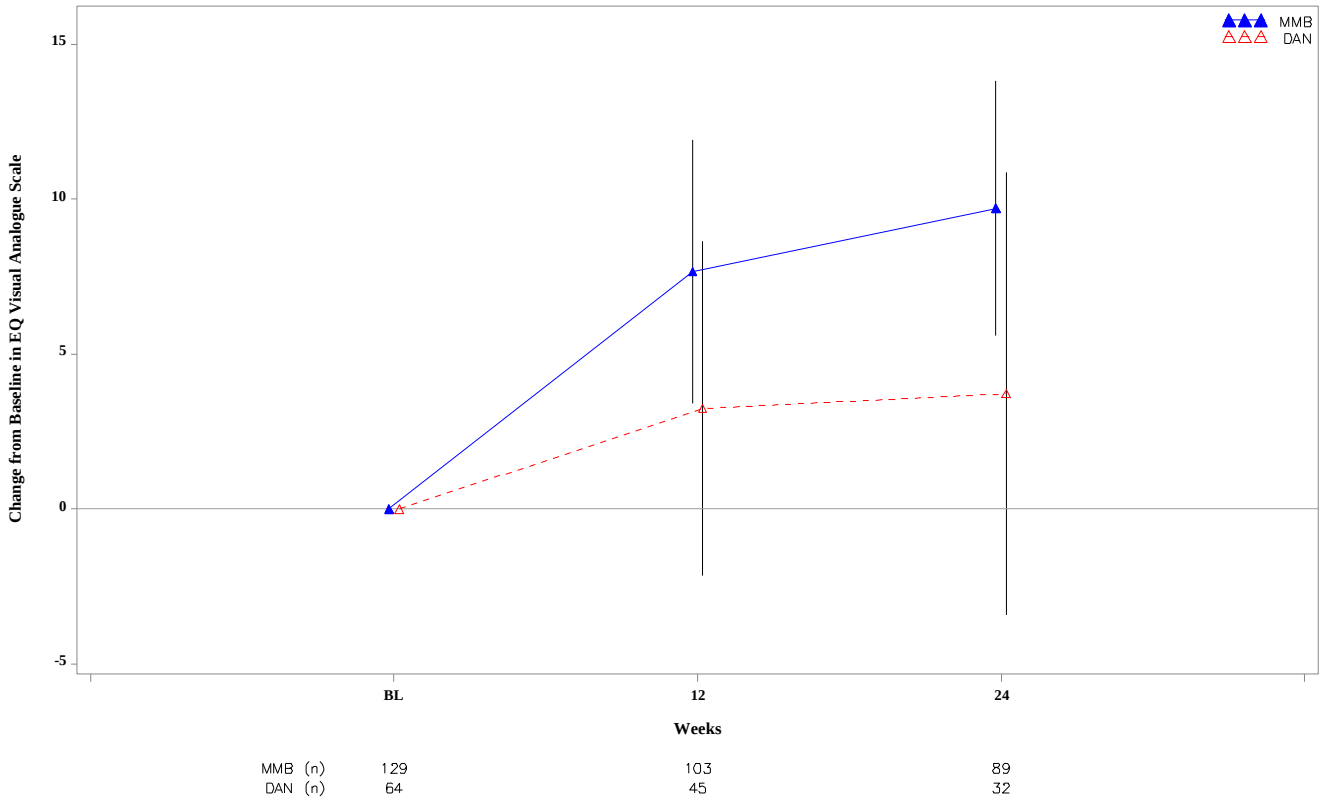
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12 cm, >=12 cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
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3.6 EQ 5D-VAS

GSK Oncology
Study SRA-MMB-301

Figure 2.0701: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in EQ Visual Analogue Scale (VAS)
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set



MMB (n)	129	103	89
DAN (n)	64	45	32

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-eq5d-chg-gba.sas V.03.05 Output file: g-eq5d-chg.pdf 31AUG2023:15:27

Table 2.1201: EQ Visual Analogue Scale (VAS) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Patients' Self Rated Score		
Baseline		
n (%)	129 (99.2%)	64 (98.5%)
Mean (SD)	49.63 (19.96)	53.77 (19.83)
Median	50.00	50.00
Q1, Q3	37.00, 62.00	42.00, 70.50
Min, Max	0.0, 98.0	10.0, 100.0
Return Rate (%)	99%	98%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	99%	98%

Notes: The EQ VAS is a self-rated scale ranging from 0 (worst imaginable health) to 100 (best imaginable health).
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eq5d-chg-gba.sas V.03.05 Output file: t-eq5d-chg.pdf 31AUG2023:16:01

Table 2.1201: EQ Visual Analogue Scale (VAS) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 12		
n (%)	104 (80.0%)	46 (70.8%)
Mean (SD)	56.62 (20.53)	60.74 (19.09)
Median	60.00	63.50
Q1, Q3	42.00, 71.00	47.00, 75.00
Min, Max	1.0, 100.0	13.0, 95.0
Change from Baseline		
n (%)	103 (79.2%)	45 (69.2%)
Mean (SD)	7.66 (21.82)	3.24 (17.94)
Median	5.00	1.00
Q1, Q3	-2.00, 20.00	-8.00, 17.00
Min, Max	-67.0, 61.0	-33.0, 40.0
Least Squares Mean (SE) [1]	7.07 (2.04)	3.55 (3.10)
95% CI [1]	3.04, 11.11	-2.57, 9.67
Least Squares Mean Difference (SE) [1]	3.53 (3.60)	
95% CI [1]	-3.58, 10.63	
p-value [2]	0.33	
Corrected Hedges' g (95% CI)	0.169 (-0.182, 0.520)	

Notes: The EQ VAS is a self-rated scale ranging from 0 (worst imaginable health) to 100 (best imaginable health).
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eq5d-chg-gba.sas V.03.05 Output file: t-eq5d-chg.pdf 31AUG2023:16:01

Table 2.1201: EQ Visual Analogue Scale (VAS) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	102 (78.5%)	45 (69.2%)
Mean (SD)	36.24 (96.24)	9.96 (37.90)
Median	13.42	2.00
Q1, Q3	-2.78, 55.26	-14.86, 31.58
Min, Max	-90.6, 677.8	-71.7, 137.9
Return Rate (%)	80%	71%
Number of Subjects in Risk	121	52
Return Rate in Risk (%)	86%	88%

Notes: The EQ VAS is a self-rated scale ranging from 0 (worst imaginable health) to 100 (best imaginable health).
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
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Table 2.1201: EQ Visual Analogue Scale (VAS) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 24		
n (%)	90 (69.2%)	33 (50.8%)
Mean (SD)	59.17 (18.25)	59.52 (18.40)
Median	60.00	60.00
Q1, Q3	50.00, 72.00	46.00, 75.00
Min, Max	5.0, 100.0	10.0, 90.0
Change from Baseline		
n (%)	89 (68.5%)	32 (49.2%)
Mean (SD)	9.70 (19.47)	3.72 (19.82)
Median	7.00	4.50
Q1, Q3	-3.00, 22.00	-10.50, 18.00
Min, Max	-36.0, 71.0	-44.0, 50.0
Least Squares Mean (SE) [1]	9.08 (2.11)	2.98 (3.41)
95% CI [1]	4.90, 13.26	-3.76, 9.72
Least Squares Mean Difference (SE) [1]	6.11 (3.89)	
95% CI [1]	-1.58, 13.79	
p-value [2]	0.12	
Corrected Hedges' g (95% CI)	0.307 (-0.099, 0.713)	

Notes: The EQ VAS is a self-rated scale ranging from 0 (worst imaginable health) to 100 (best imaginable health).
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
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Table 2.1201: EQ Visual Analogue Scale (VAS) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	88 (67.7%)	32 (49.2%)
Mean (SD)	39.35 (90.35)	11.85 (41.04)
Median	13.39	8.26
Q1, Q3	-5.74, 53.43	-17.69, 34.99
Min, Max	-73.7, 507.1	-78.3, 125.0
Return Rate (%)	69%	51%
Number of Subjects in Risk	101	39
Return Rate in Risk (%)	89%	85%

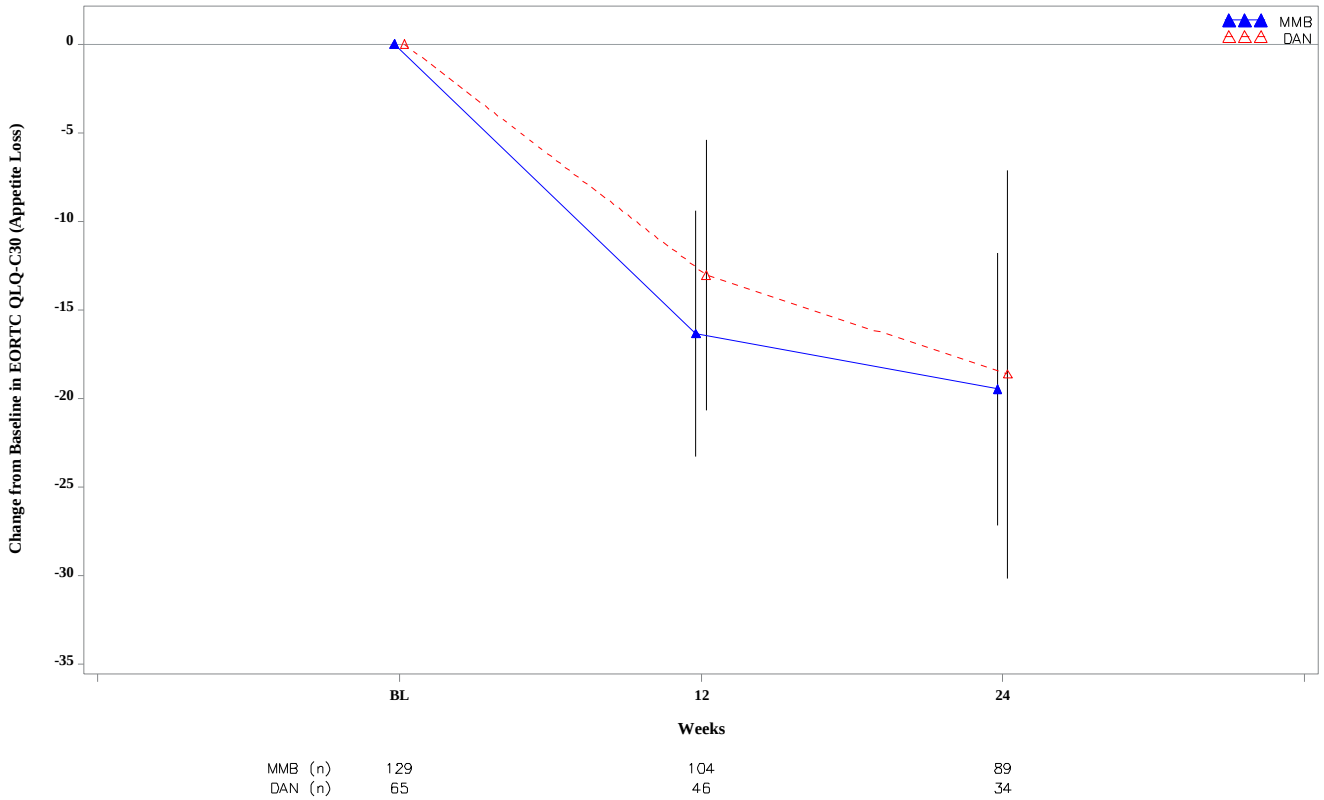
Notes: The EQ VAS is a self-rated scale ranging from 0 (worst imaginable health) to 100 (best imaginable health).
[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
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3.7 EORTC

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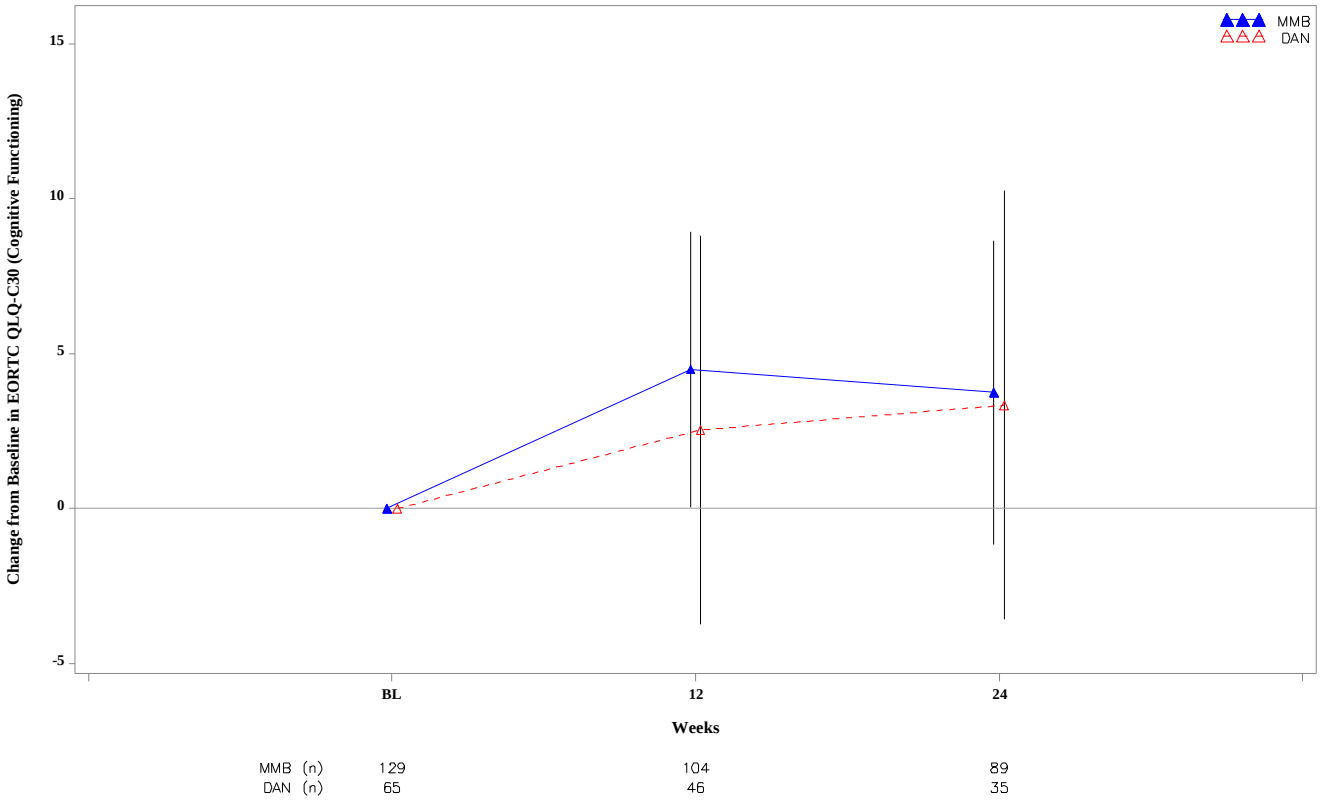
Figure 2.0406: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Cancer-Related Appetite Loss (EORTC QLQ-C30)
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set



MMB (n)	129	104	89
DAN (n)	65	46	34

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-eortc-chg-gba.sas V.03.05 Output file: g-eortc-chg-appet.pdf 31AUG2023:15:27

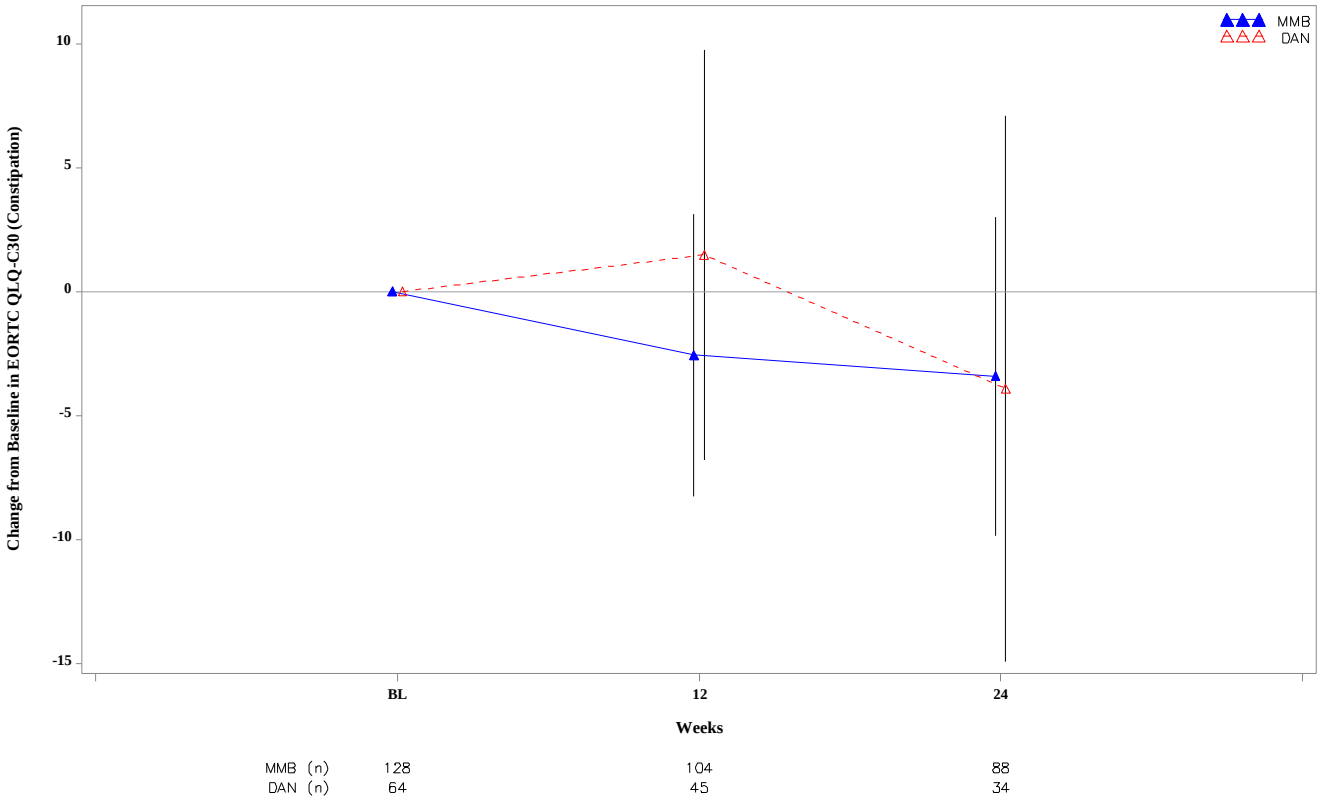
Figure 2.0413: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Cognitive Functioning Score (EORTC QLQ-C30)
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set



MMB (n)	129	104	89
DAN (n)	65	46	35

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-eortc-chg-gba.sas V.03.05 Output file: g-eortc-chg-cogn.pdf 31AUG2023:15:27

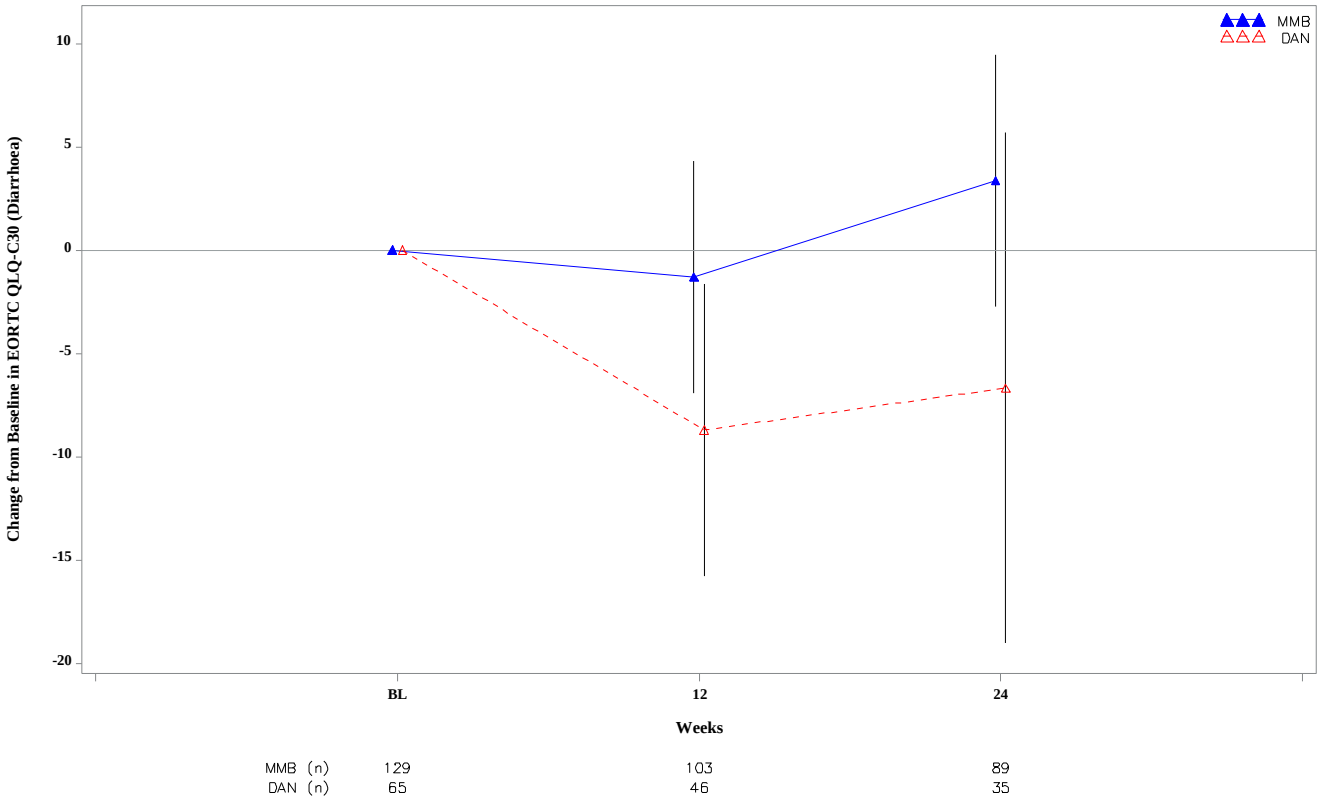
Figure 2.0407: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Cancer-Related Constipation (EORTC QLQ-C30)
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set



	BL	12	24
MMB (n)	128	104	88
DAN (n)	64	45	34

Data Extracted: CRF data: 13JAN2022
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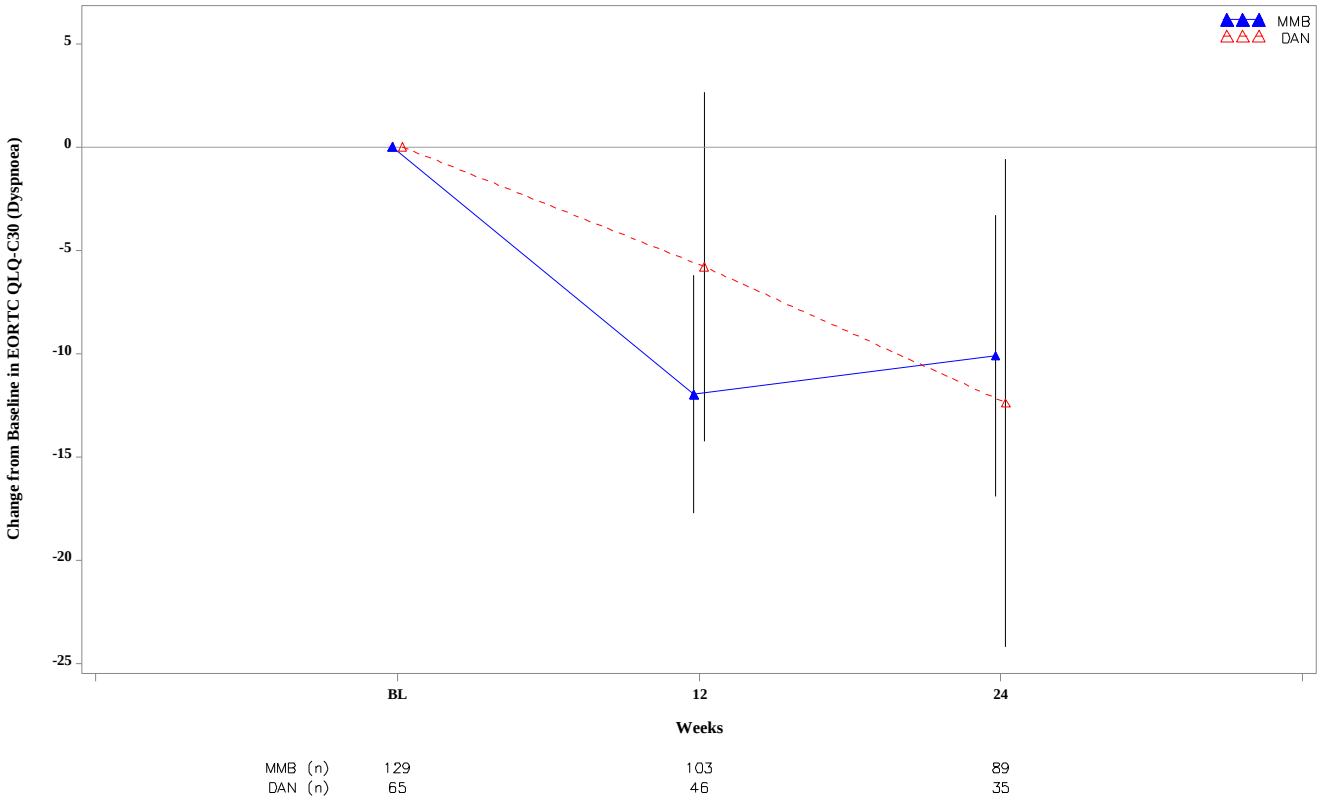
Figure 2.0408: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Cancer-Related Diarrhoea (EORTC QLQ-C30)
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set



	BL	12	24
MMB (n)	129	103	89
DAN (n)	65	46	35

Data Extracted: CRF data: 13JAN2022
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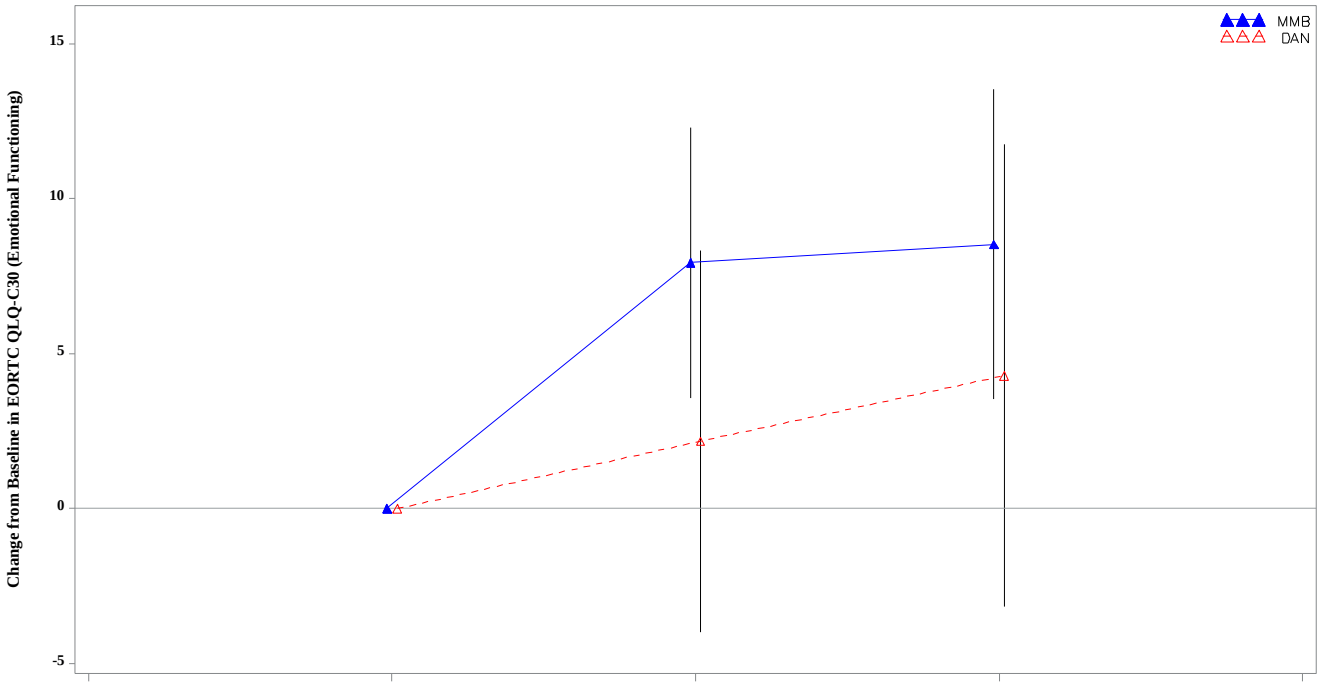
Figure 2.0404: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Cancer-Related Dyspnoea (EORTC QLQ-C30)
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set



	BL	12	24
MMB (n)	129	103	89
DAN (n)	65	46	35

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-eortc-chg-gba.sas V.03.05 Output file: g-eortc-chg-dysp.pdf 31AUG2023:15:27

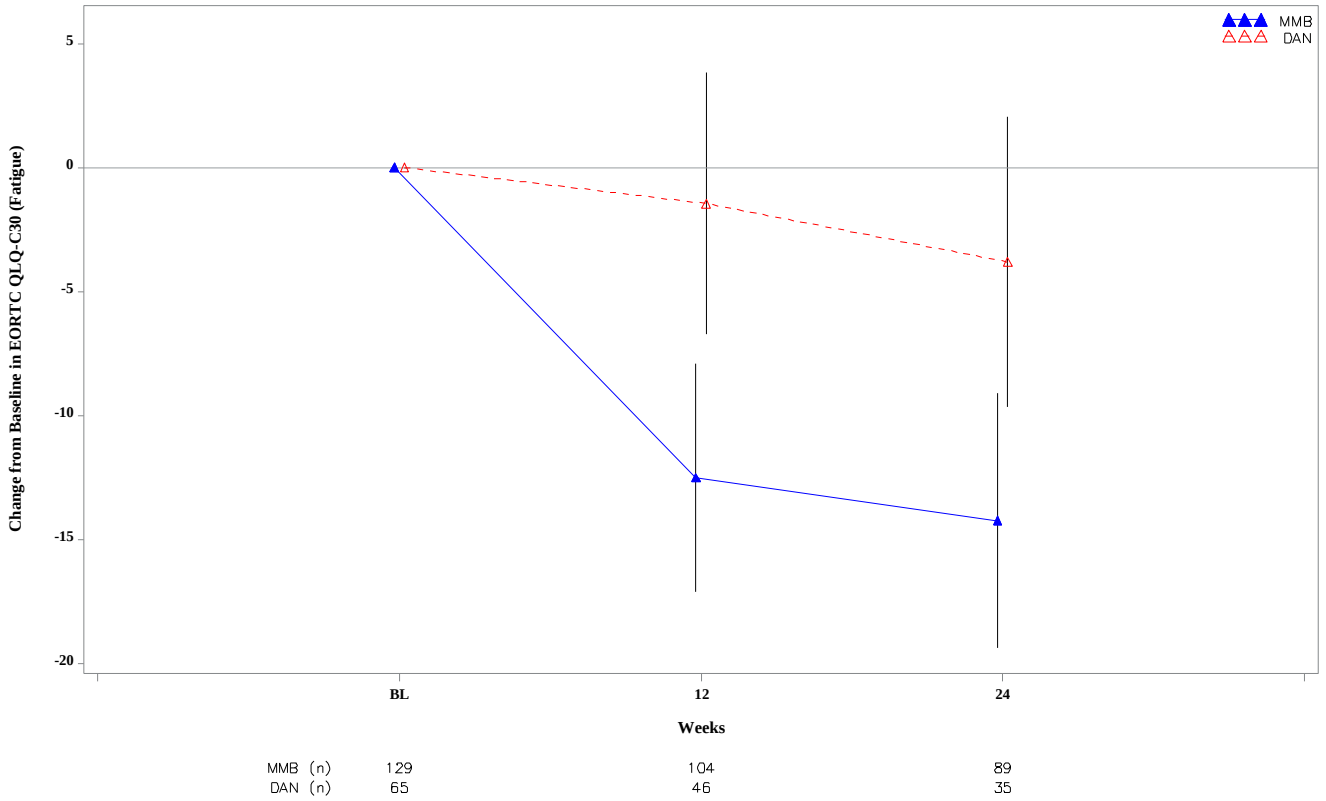
Figure 2.0412: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Emotional Functioning Score (EORTC QLQ-C30)
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set



MMB (n)	129	104	89
DAN (n)	65	46	35

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-eortc-chg-gba.sas V.03.05 Output file: g-eortc-chg-emot.pdf 31AUG2023:15:27

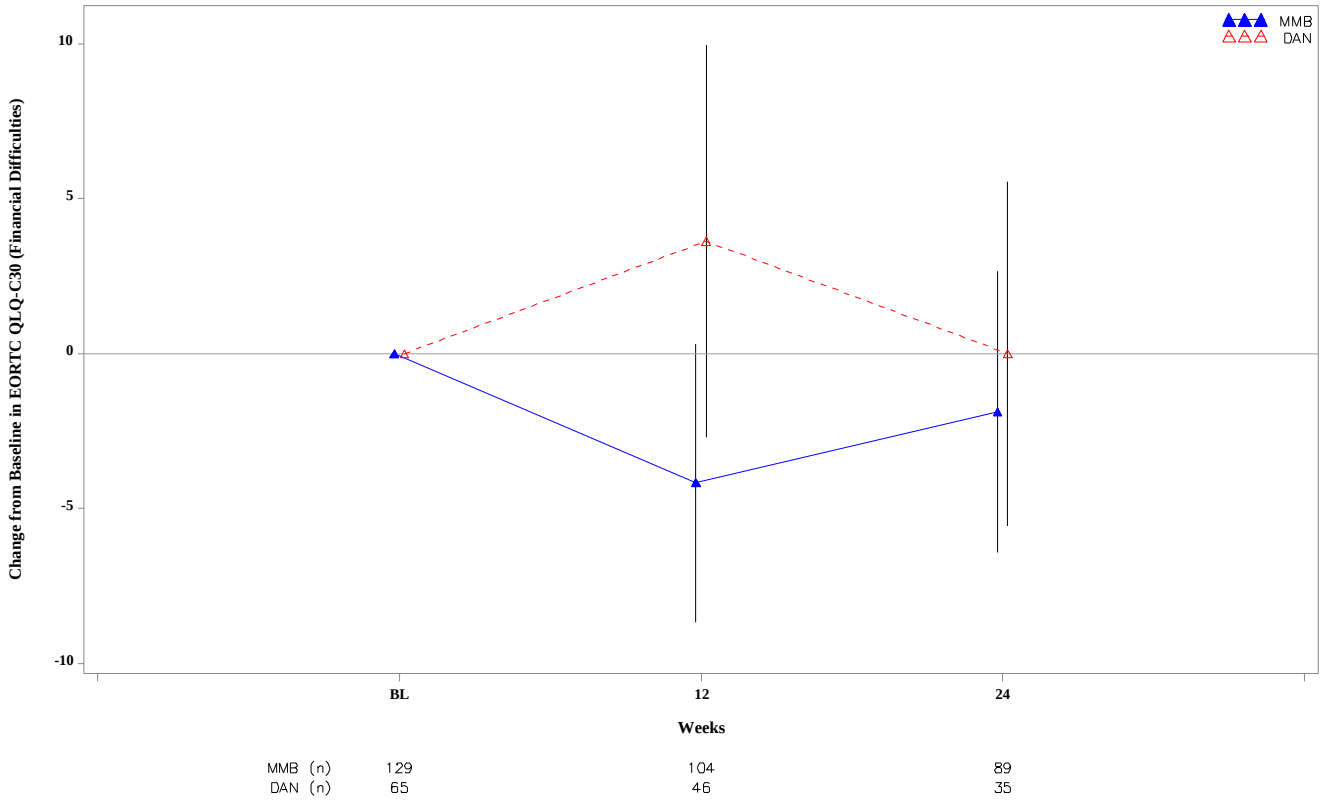
Figure 2.0401: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Cancer-Related Fatigue (EORTC QLQ-C30)
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set



	BL	12	24
MMB (n)	129	104	89
DAN (n)	65	46	35

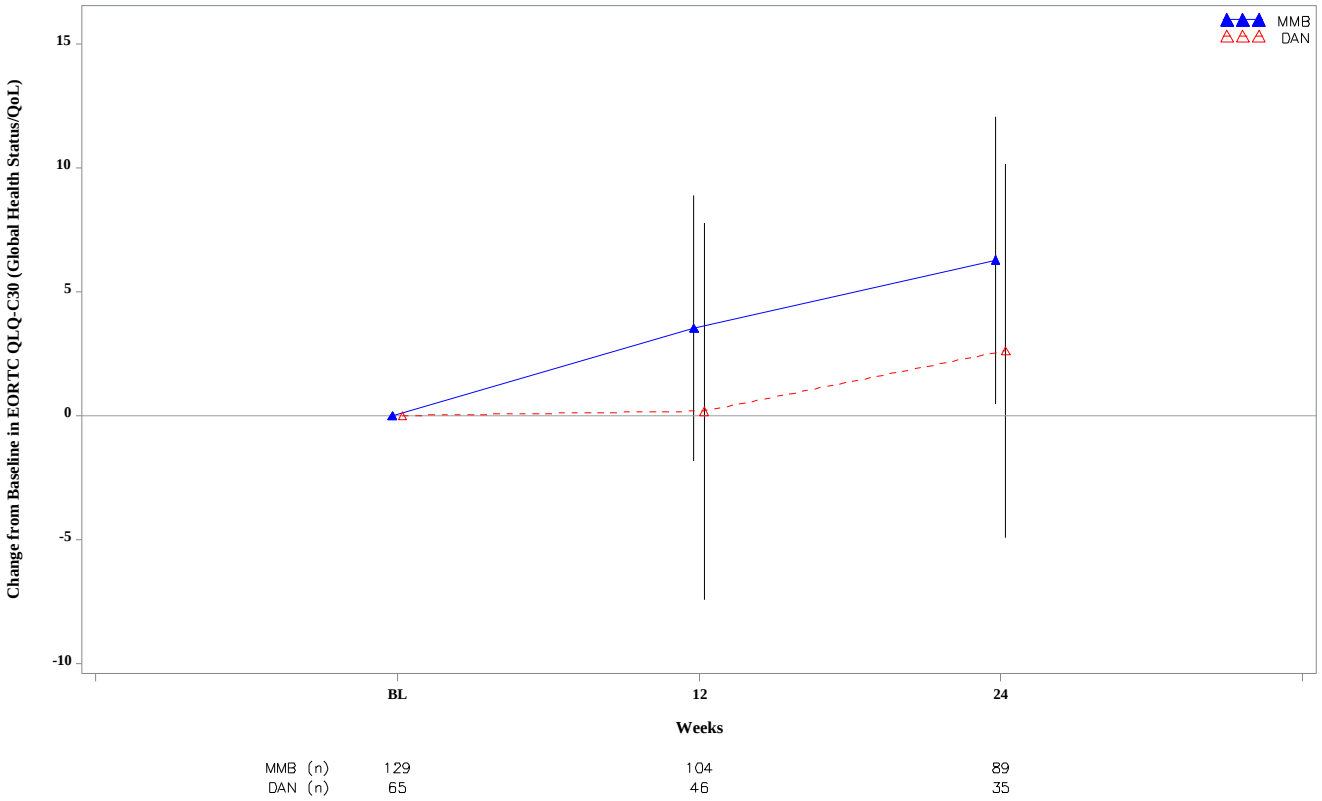
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Figure 2.0409: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Cancer-Related Financial Difficulties (EORTC QLQ-C30)
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set



MMB (n)	129	104	89
DAN (n)	65	46	35

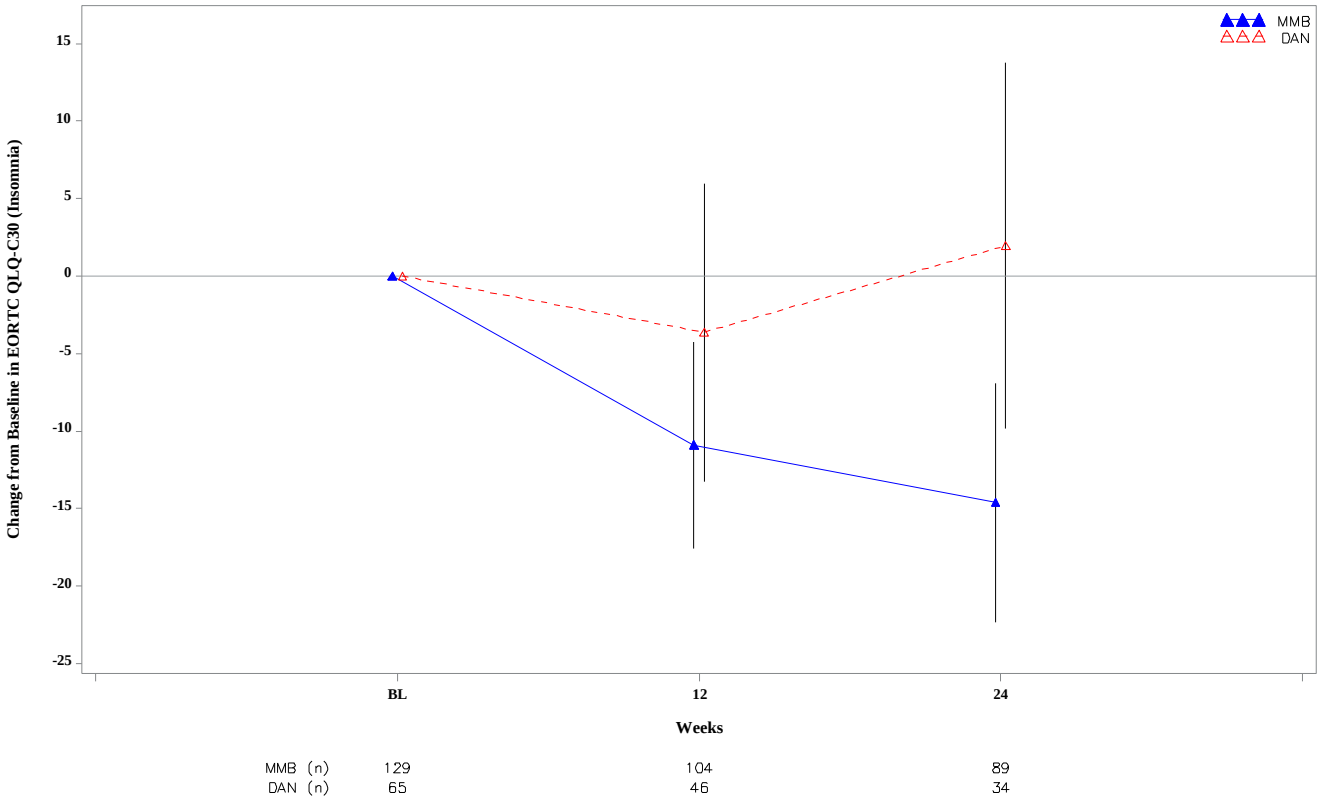
Figure 2.0415: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Global Health Status/QoL (EORTC QLQ-C30)
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set



MMB (n)	129	104	89
DAN (n)	65	46	35

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-eortc-chg-gba.sas V.03.05 Output file: g-eortc-chg-global.pdf 31AUG2023:15:27

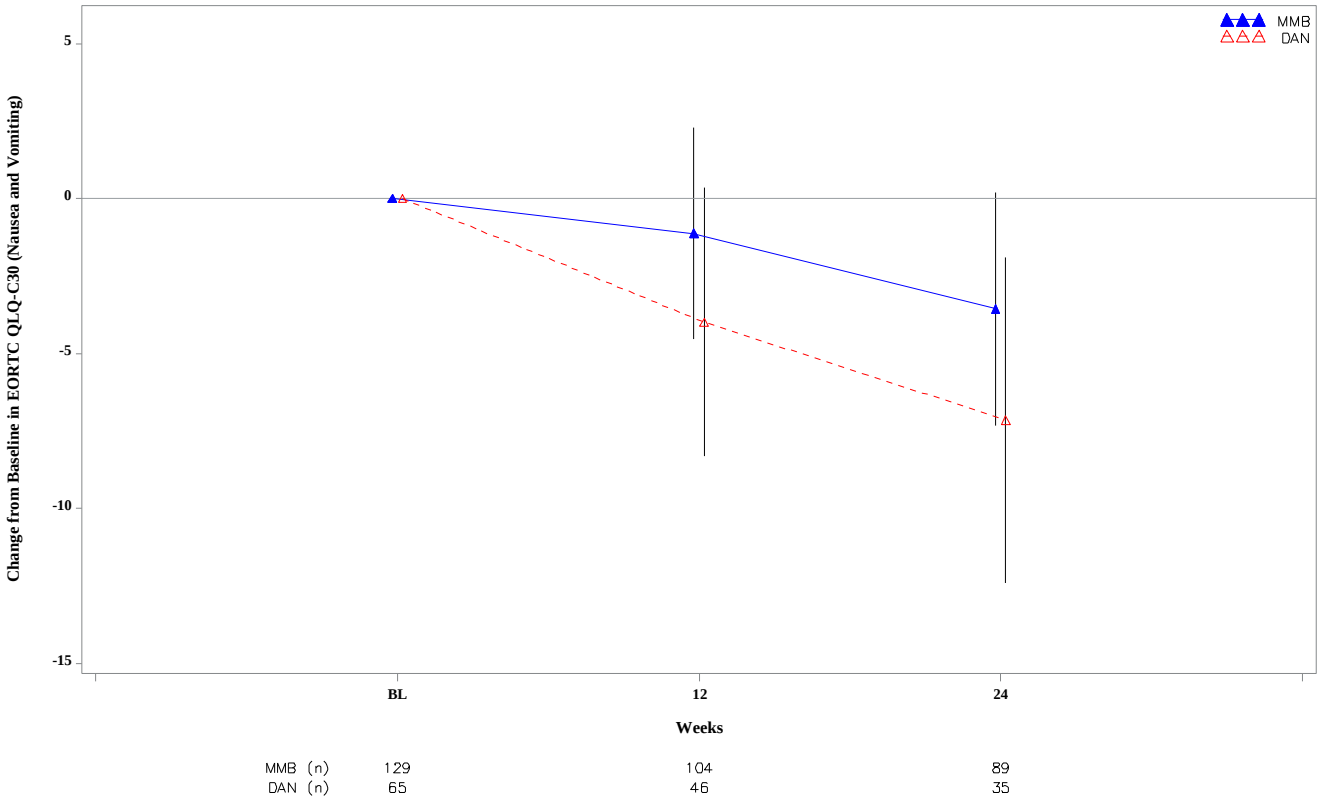
Figure 2.0405: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Cancer-Related Insomnia (EORTC QLQ-C30)
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set



MMB (n)	129	104	89
DAN (n)	65	46	34

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-eortc-chg-gba.sas V.03.05 Output file: g-eortc-chg-insom.pdf 31AUG2023:15:27

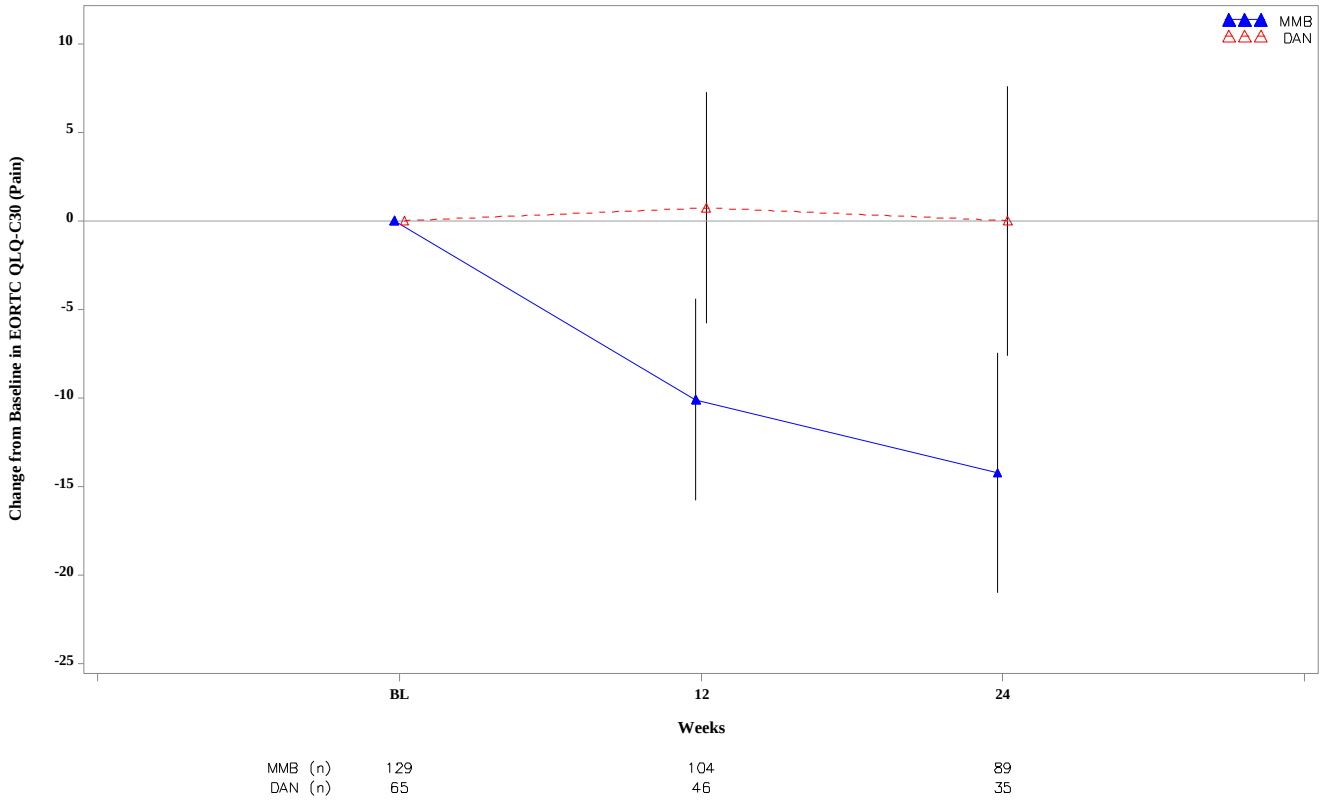
Figure 2.0402: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Cancer-Related Nausea and Vomiting (EORTC QLQ-C30)
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set



MMB (n)	129	104	89
DAN (n)	65	46	35

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-eortc-chg-gba.sas V.03.05 Output file: g-eortc-chg-naus.pdf 31AUG2023:15:27

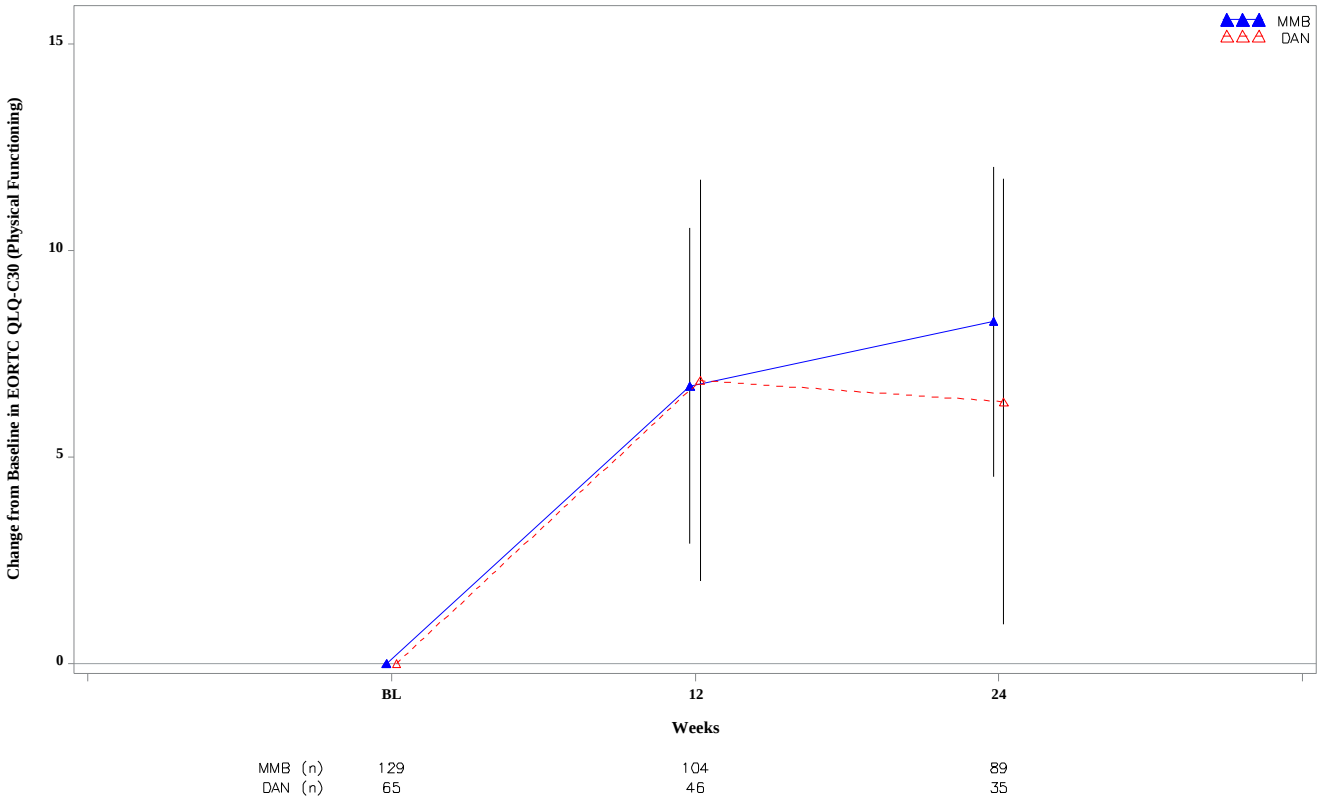
Figure 2.0403: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Cancer-Related Pain (EORTC QLQ-C30)
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set



MMB (n)	129	104	89
DAN (n)	65	46	35

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-eortc-chg-gba.sas V.03.05 Output file: g-eortc-chg-pain.pdf 31AUG2023:15:27

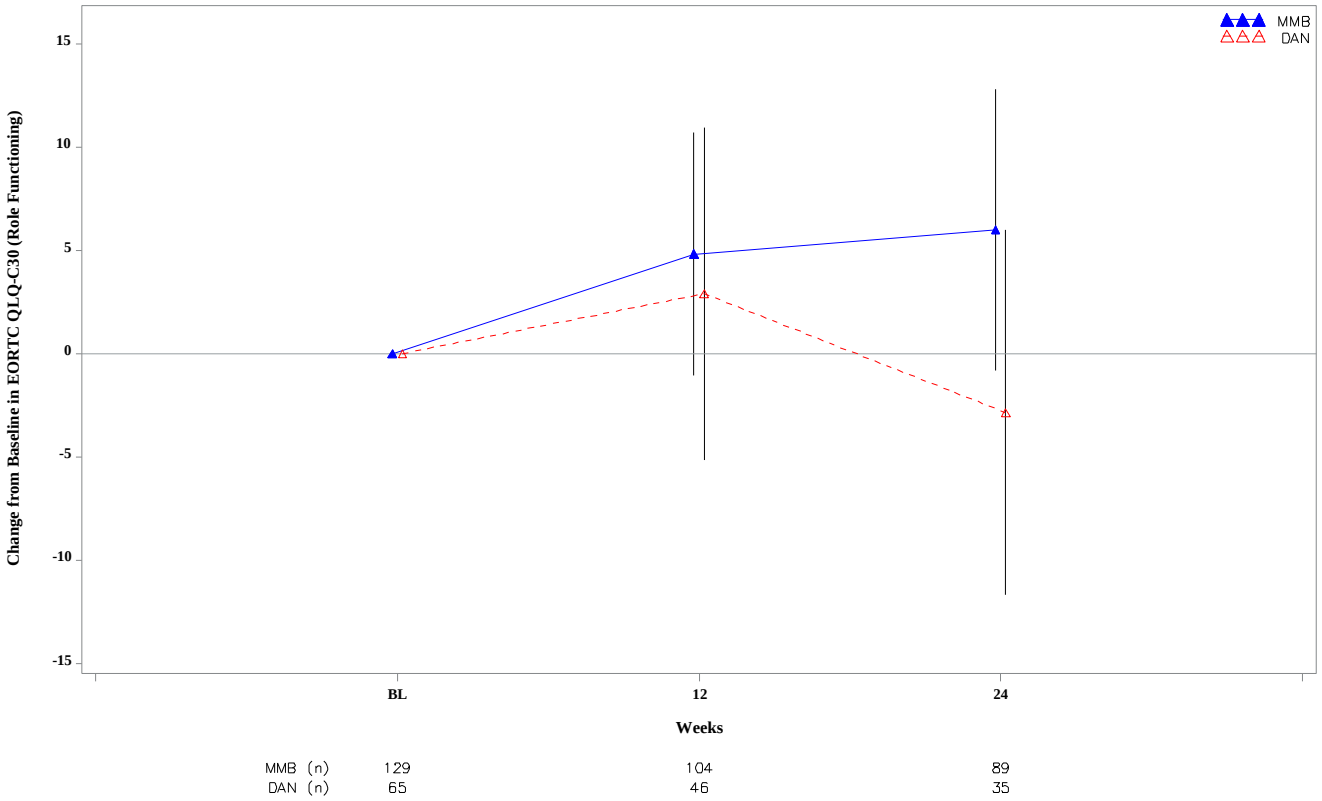
Figure 2.0410: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Physical Functioning Score (EORTC QLQ-C30)
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set



MMB (n)	129	104	89
DAN (n)	65	46	35

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-eortc-chg-gba.sas V.03.05 Output file: g-eortc-chg-phys.pdf 31AUG2023:15:27

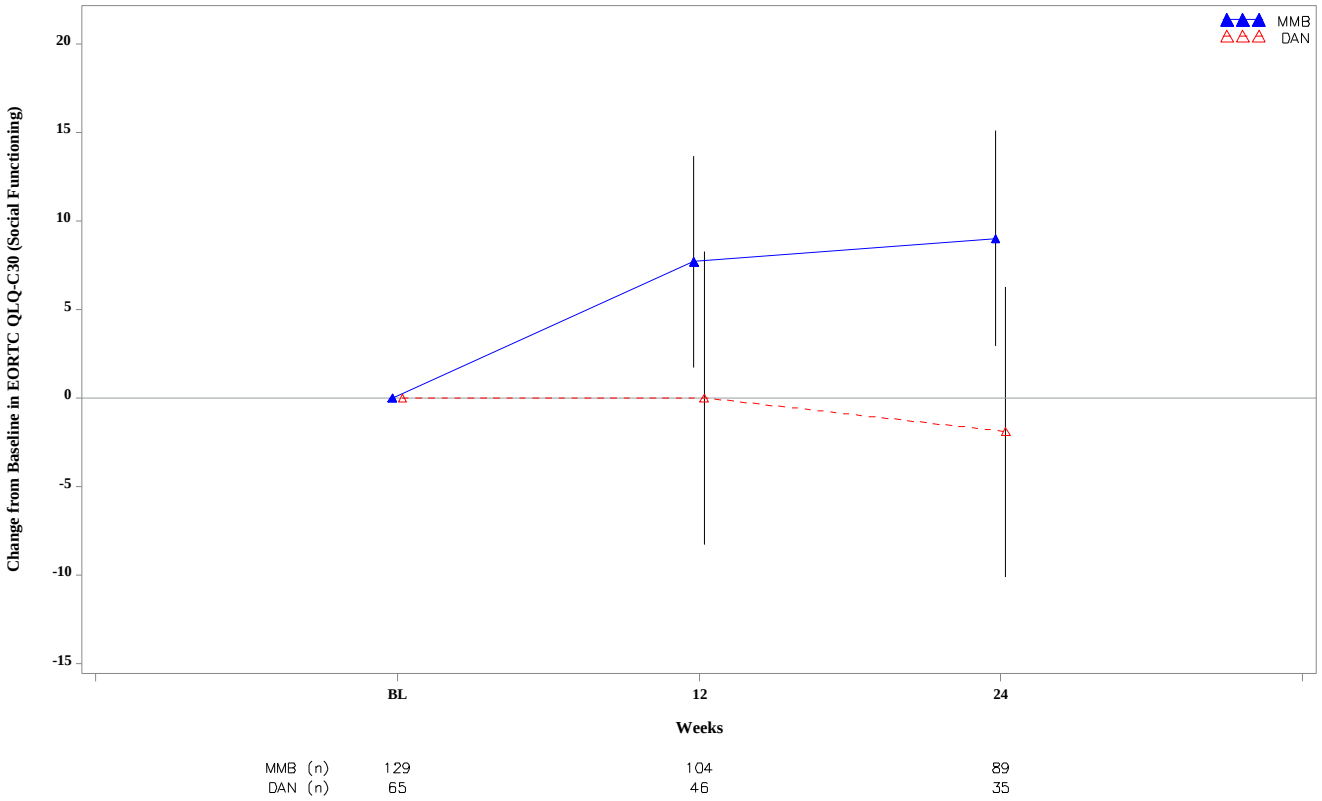
Figure 2.0411: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Role Functioning Score (EORTC QLQ-C30)
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set



MMB (n)	129	104	89
DAN (n)	65	46	35

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-eortc-chg-gba.sas V.03.05 Output file: g-eortc-chg-role.pdf 31AUG2023:15:27

Figure 2.0414: Mean (incl. 95% CI) Plot of Change from Baseline (including Baseline) in Social Functioning Score (EORTC QLQ-C30)
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set



MMB (n)	129	104	89
DAN (n)	65	46	35

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/g-eortc-chg-gba.sas V.03.05 Output file: g-eortc-chg-social.pdf 31AUG2023:15:27

Table 2.0806: Cancer-Related Appetite Loss (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
EORTC QLQ-C30 Appetite Loss		
Baseline		
n (%)	129 (99.2%)	65 (100.0%)
Mean (SD)	42.38 (31.94)	37.44 (32.01)
Median	33.33	33.33
Q1, Q3	33.33, 66.67	0.00, 66.67
Min, Max	0.0, 100.0	0.0, 100.0
Return Rate (%)	99%	100%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	99%	100%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
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Table 2.0806: Cancer-Related Appetite Loss (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 12		
n (%)	105 (80.8%)	46 (70.8%)
Mean (SD)	25.40 (31.53)	21.74 (24.56)
Median	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline		
n (%)	104 (80.0%)	46 (70.8%)
Mean (SD)	-16.35 (35.68)	-13.04 (25.80)
Median	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
Min, Max	-100.0, 66.7	-66.7, 33.3
Least Squares Mean (SE) [1]	-15.18 (3.35)	-11.63 (5.02)
95% CI [1]	-21.79, -8.56	-21.55, -1.71
Least Squares Mean Difference (SE) [1]	-3.54 (5.85)	
95% CI [1]	-15.10, 8.01	
p-value [2]	0.55	
Corrected Hedges' g (95% CI)	-0.103 (-0.451, 0.244)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.0806: Cancer-Related Appetite Loss (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	98 (75.4%)	43 (66.2%)
Mean (SD)	-31.29 (64.63)	-30.23 (46.61)
Median	0.00	0.00
Q1, Q3	-100.00, 0.00	-66.67, 0.00
Min, Max	-100.0, 200.0	-100.0, 100.0
Return Rate (%)	81%	71%
Number of Subjects in Risk	121	52
Return Rate in Risk (%)	87%	88%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
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Table 2.0806: Cancer-Related Appetite Loss (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 24		
n (%)	90 (69.2%)	34 (52.3%)
Mean (SD)	24.07 (30.81)	21.57 (30.58)
Median	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline		
n (%)	89 (68.5%)	34 (52.3%)
Mean (SD)	-19.48 (36.52)	-18.63 (33.02)
Median	0.00	-16.67
Q1, Q3	-33.33, 0.00	-33.33, 0.00
Min, Max	-100.0, 66.7	-100.0, 66.7
Least Squares Mean (SE) [1]	-16.49 (3.69)	-14.73 (5.78)
95% CI [1]	-23.79, -9.20	-26.15, -3.32
Least Squares Mean Difference (SE) [1]	-1.76 (6.67)	
95% CI [1]	-14.94, 11.42	
p-value [2]	0.79	
Corrected Hedges' g (95% CI)	-0.051 (-0.446, 0.345)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-appet.pdf 31AUG2023:16:00

Table 2.0806: Cancer-Related Appetite Loss (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	85 (65.4%)	33 (50.8%)
Mean (SD)	-33.53 (61.80)	-35.35 (63.29)
Median	0.00	-50.00
Q1, Q3	-100.00, 0.00	-100.00, 0.00
Min, Max	-100.0, 200.0	-100.0, 200.0
Return Rate (%)	69%	52%
Number of Subjects in Risk	101	39
Return Rate in Risk (%)	89%	87%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-appet.pdf 31AUG2023:16:00

Table 2.0904: EORTC QLQ-C30 Change From Baseline - Cognitive Functioning
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
EORTC QLQ-C30 Cognitive Functioning		
Baseline		
n (%)	129 (99.2%)	65 (100.0%)
Mean (SD)	76.61 (22.78)	77.95 (21.47)
Median	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
Min, Max	0.0, 100.0	33.3, 100.0
Return Rate (%)	99%	100%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	99%	100%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.0904: EORTC QLQ-C30 Change From Baseline - Cognitive Functioning
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 12		
n (%)	105 (80.8%)	46 (70.8%)
Mean (SD)	80.79 (19.99)	84.42 (20.00)
Median	83.33	83.33
Q1, Q3	66.67, 100.00	83.33, 100.00
Min, Max	0.0, 100.0	16.7, 100.0
Change from Baseline		
n (%)	104 (80.0%)	46 (70.8%)
Mean (SD)	4.49 (22.90)	2.54 (21.07)
Median	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 16.67
Min, Max	-83.3, 66.7	-50.0, 66.7
Least Squares Mean (SE) [1]	4.99 (2.25)	3.88 (3.38)
95% CI [1]	0.54, 9.44	-2.80, 10.55
Least Squares Mean Difference (SE) [1]	1.11 (3.94)	
95% CI [1]	-6.67, 8.89	
p-value [2]	0.78	
Corrected Hedges' g (95% CI)	0.048 (-0.299, 0.395)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.0904: EORTC QLQ-C30 Change From Baseline - Cognitive Functioning
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	103 (79.2%)	46 (70.8%)
Mean (SD)	13.12 (44.56)	8.48 (39.78)
Median	0.00	0.00
Q1, Q3	0.00, 25.00	0.00, 20.00
Min, Max	-100.0, 200.0	-75.0, 200.0
Return Rate (%)	81%	71%
Number of Subjects in Risk	121	52
Return Rate in Risk (%)	87%	88%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-cogn.pdf 31AUG2023:16:00

Table 2.0904: EORTC QLQ-C30 Change From Baseline - Cognitive Functioning
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 24		
n (%)	90 (69.2%)	35 (53.8%)
Mean (SD)	80.37 (18.46)	81.90 (18.24)
Median	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
Min, Max	0.0, 100.0	33.3, 100.0
Change from Baseline		
n (%)	89 (68.5%)	35 (53.8%)
Mean (SD)	3.75 (23.27)	3.33 (20.13)
Median	0.00	0.00
Q1, Q3	-16.67, 16.67	0.00, 16.67
Min, Max	-66.7, 66.7	-50.0, 50.0
Least Squares Mean (SE) [1]	3.42 (2.33)	2.39 (3.61)
95% CI [1]	-1.19, 8.03	-4.74, 9.51
Least Squares Mean Difference (SE) [1]	1.04 (4.16)	
95% CI [1]	-7.19, 9.26	
p-value [2]	0.80	
Corrected Hedges' g (95% CI)	0.047 (-0.344, 0.438)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.0904: EORTC QLQ-C30 Change From Baseline - Cognitive Functioning
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	88 (67.7%)	35 (53.8%)
Mean (SD)	13.64 (48.11)	9.29 (34.75)
Median	0.00	0.00
Q1, Q3	-16.67, 25.00	0.00, 25.00
Min, Max	-100.0, 200.0	-50.0, 150.0
Return Rate (%)	69%	54%
Number of Subjects in Risk	101	39
Return Rate in Risk (%)	89%	90%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-cogn.pdf 31AUG2023:16:00

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Table 2.0807: Cancer-Related Constipation (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
EORTC QLQ-C30 Constipation		
Baseline		
n (%)	128 (98.5%)	64 (98.5%)
Mean (SD)	16.41 (23.66)	13.54 (24.28)
Median	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
Min, Max	0.0, 100.0	0.0, 100.0
Return Rate (%)	98%	98%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	98%	98%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-const.pdf 31AUG2023:16:00

Table 2.0807: Cancer-Related Constipation (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 12		
n (%)	105 (80.8%)	46 (70.8%)
Mean (SD)	13.65 (24.33)	13.04 (24.82)
Median	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline		
n (%)	104 (80.0%)	45 (69.2%)
Mean (SD)	-2.56 (29.26)	1.48 (27.48)
Median	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
Min, Max	-100.0, 100.0	-100.0, 66.7
Least Squares Mean (SE) [1]	-2.23 (2.89)	3.03 (4.36)
95% CI [1]	-7.93, 3.47	-5.57, 11.64
Least Squares Mean Difference (SE) [1]	-5.26 (5.08)	
95% CI [1]	-15.29, 4.77	
p-value [2]	0.30	
Corrected Hedges' g (95% CI)	-0.178 (-0.529, 0.172)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.0807: Cancer-Related Constipation (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	92 (70.8%)	39 (60.0%)
Mean (SD)	-15.76 (50.24)	-6.41 (56.40)
Median	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
Min, Max	-100.0, 200.0	-100.0, 200.0
Return Rate (%)	81%	71%
Number of Subjects in Risk	121	52
Return Rate in Risk (%)	87%	88%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-const.pdf 31AUG2023:16:00

Table 2.0807: Cancer-Related Constipation (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 24		
n (%)	90 (69.2%)	35 (53.8%)
Mean (SD)	14.44 (20.63)	10.48 (22.54)
Median	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
Min, Max	0.0, 66.7	0.0, 100.0
Change from Baseline		
n (%)	88 (67.7%)	34 (52.3%)
Mean (SD)	-3.41 (30.34)	-3.92 (31.53)
Median	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
Min, Max	-100.0, 66.7	-100.0, 66.7
Least Squares Mean (SE) [1]	-1.30 (3.15)	-1.40 (4.93)
95% CI [1]	-7.53, 4.94	-11.15, 8.34
Least Squares Mean Difference (SE) [1]	0.11 (5.70)	
95% CI [1]	-11.17, 11.38	
p-value [2]	0.99	
Corrected Hedges' g (95% CI)	0.004 (-0.392, 0.399)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.0807: Cancer-Related Constipation (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	74 (56.9%)	30 (46.2%)
Mean (SD)	-23.87 (44.92)	-18.33 (59.43)
Median	0.00	0.00
Q1, Q3	-50.00, 0.00	-50.00, 0.00
Min, Max	-100.0, 100.0	-100.0, 200.0
Return Rate (%)	69%	54%
Number of Subjects in Risk	101	39
Return Rate in Risk (%)	89%	90%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-const.pdf 31AUG2023:16:00

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Table 2.0808: Cancer-Related Diarrhoea (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
EORTC QLQ-C30 Diarrhoea		
Baseline		
n (%)	129 (99.2%)	65 (100.0%)
Mean (SD)	17.31 (26.39)	21.54 (25.30)
Median	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
Min, Max	0.0, 100.0	0.0, 100.0
Return Rate (%)	99%	100%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	99%	100%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.0808: Cancer-Related Diarrhoea (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 12		
n (%)	104 (80.0%)	46 (70.8%)
Mean (SD)	16.35 (24.58)	11.59 (20.14)
Median	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
Min, Max	0.0, 100.0	0.0, 66.7
Change from Baseline		
n (%)	103 (79.2%)	46 (70.8%)
Mean (SD)	-1.29 (28.74)	-8.70 (23.76)
Median	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
Min, Max	-100.0, 100.0	-66.7, 33.3
Least Squares Mean (SE) [1]	-1.45 (2.77)	-9.65 (4.13)
95% CI [1]	-6.92, 4.02	-17.82, -1.49
Least Squares Mean Difference (SE) [1]	8.21 (4.82)	
95% CI [1]	-1.32, 17.74	
p-value [2]	0.091	
Corrected Hedges' g (95% CI)	0.291 (-0.058, 0.640)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.0808: Cancer-Related Diarrhoea (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	87 (66.9%)	42 (64.6%)
Mean (SD)	-15.71 (49.76)	-29.37 (49.36)
Median	0.00	0.00
Q1, Q3	-50.00, 0.00	-100.00, 0.00
Min, Max	-100.0, 200.0	-100.0, 100.0
Return Rate (%)	80%	71%
Number of Subjects in Risk	121	52
Return Rate in Risk (%)	86%	88%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-diarr.pdf 31AUG2023:16:00

Table 2.0808: Cancer-Related Diarrhoea (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 24		
n (%)	90 (69.2%)	35 (53.8%)
Mean (SD)	18.15 (26.04)	13.33 (25.82)
Median	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline		
n (%)	89 (68.5%)	35 (53.8%)
Mean (SD)	3.37 (28.89)	-6.67 (35.97)
Median	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
Min, Max	-100.0, 100.0	-66.7, 100.0
Least Squares Mean (SE) [1]	1.10 (3.26)	-6.84 (5.08)
95% CI [1]	-5.33, 7.54	-16.88, 3.21
Least Squares Mean Difference (SE) [1]	7.94 (5.89)	
95% CI [1]	-3.70, 19.58	
p-value [2]	0.18	
Corrected Hedges' g (95% CI)	0.258 (-0.134, 0.651)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.0808: Cancer-Related Diarrhoea (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	71 (54.6%)	31 (47.7%)
Mean (SD)	-9.15 (50.22)	-30.65 (58.70)
Median	0.00	0.00
Q1, Q3	0.00, 0.00	-100.00, 0.00
Min, Max	-100.0, 200.0	-100.0, 100.0
Return Rate (%)	69%	54%
Number of Subjects in Risk	101	39
Return Rate in Risk (%)	89%	90%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-diarr.pdf 31AUG2023:16:00

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Table 2.0804: Cancer-Related Dyspnoea (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
EORTC QLQ-C30 Dyspnoea		
Baseline		
n (%)	129 (99.2%)	65 (100.0%)
Mean (SD)	40.57 (31.99)	42.05 (32.95)
Median	33.33	33.33
Q1, Q3	0.00, 66.67	0.00, 66.67
Min, Max	0.0, 100.0	0.0, 100.0
Return Rate (%)	99%	100%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	99%	100%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.0804: Cancer-Related Dyspnoea (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 12		
n (%)	104 (80.0%)	46 (70.8%)
Mean (SD)	28.53 (29.89)	34.78 (29.78)
Median	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline		
n (%)	103 (79.2%)	46 (70.8%)
Mean (SD)	-11.97 (29.47)	-5.80 (28.38)
Median	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
Min, Max	-100.0, 66.7	-66.7, 33.3
Least Squares Mean (SE) [1]	-11.56 (2.96)	-5.45 (4.43)
95% CI [1]	-17.41, -5.71	-14.20, 3.31
Least Squares Mean Difference (SE) [1]	-6.11 (5.15)	
95% CI [1]	-16.30, 4.07	
p-value [2]	0.24	
Corrected Hedges' g (95% CI)	-0.202 (-0.551, 0.146)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.0804: Cancer-Related Dyspnoea (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	97 (74.6%)	40 (61.5%)
Mean (SD)	-25.26 (49.72)	-21.67 (52.73)
Median	0.00	0.00
Q1, Q3	-50.00, 0.00	-50.00, 0.00
Min, Max	-100.0, 100.0	-100.0, 100.0
Return Rate (%)	80%	71%
Number of Subjects in Risk	121	52
Return Rate in Risk (%)	86%	88%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-dysp.pdf 31AUG2023:16:00

Table 2.0804: Cancer-Related Dyspnoea (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 24		
n (%)	90 (69.2%)	35 (53.8%)
Mean (SD)	30.37 (29.83)	30.48 (27.26)
Median	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline		
n (%)	89 (68.5%)	35 (53.8%)
Mean (SD)	-10.11 (32.34)	-12.38 (34.38)
Median	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
Min, Max	-100.0, 66.7	-66.7, 66.7
Least Squares Mean (SE) [1]	-9.65 (3.42)	-9.75 (5.30)
95% CI [1]	-16.41, -2.89	-20.23, 0.72
Least Squares Mean Difference (SE) [1]	0.10 (6.15)	
95% CI [1]	-12.05, 12.25	
p-value [2]	0.99	
Corrected Hedges' g (95% CI)	0.003 (-0.388, 0.394)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-dysp.pdf 31AUG2023:16:00

Table 2.0804: Cancer-Related Dyspnoea (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	82 (63.1%)	31 (47.7%)
Mean (SD)	-22.15 (57.80)	-32.26 (51.99)
Median	0.00	-50.00
Q1, Q3	-66.67, 0.00	-66.67, 0.00
Min, Max	-100.0, 200.0	-100.0, 100.0
Return Rate (%)	69%	54%
Number of Subjects in Risk	101	39
Return Rate in Risk (%)	89%	90%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-dysp.pdf 31AUG2023:16:00

Table 2.0903: EORTC QLQ-C30 Change From Baseline - Emotional Functioning
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
EORTC QLQ-C30 Emotional Functioning		
Baseline		
n (%)	129 (99.2%)	65 (100.0%)
Mean (SD)	66.49 (24.22)	70.90 (19.88)
Median	66.67	75.00
Q1, Q3	50.00, 83.33	58.33, 83.33
Min, Max	0.0, 100.0	16.7, 100.0
Return Rate (%)	99%	100%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	99%	100%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.0903: EORTC QLQ-C30 Change From Baseline - Emotional Functioning
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 12		
n (%)	105 (80.8%)	46 (70.8%)
Mean (SD)	75.32 (21.18)	74.82 (22.94)
Median	83.33	83.33
Q1, Q3	66.67, 91.67	66.67, 91.67
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline		
n (%)	104 (80.0%)	46 (70.8%)
Mean (SD)	7.93 (22.38)	2.17 (20.74)
Median	8.33	0.00
Q1, Q3	-4.17, 20.83	-8.33, 16.67
Min, Max	-58.3, 83.3	-58.3, 58.3
Least Squares Mean (SE) [1]	8.14 (2.18)	2.93 (3.27)
95% CI [1]	3.83, 12.45	-3.54, 9.40
Least Squares Mean Difference (SE) [1]	5.21 (3.81)	
95% CI [1]	-2.32, 12.73	
p-value [2]	0.17	
Corrected Hedges' g (95% CI)	0.233 (-0.115, 0.581)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.0903: EORTC QLQ-C30 Change From Baseline - Emotional Functioning
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	103 (79.2%)	46 (70.8%)
Mean (SD)	29.64 (109.82)	7.07 (39.17)
Median	9.09	0.00
Q1, Q3	-8.33, 37.50	-10.00, 22.22
Min, Max	-100.0, 1000.0	-100.0, 140.0
Return Rate (%)	81%	71%
Number of Subjects in Risk	121	52
Return Rate in Risk (%)	87%	88%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-emot.pdf 31AUG2023:16:00

Table 2.0903: EORTC QLQ-C30 Change From Baseline - Emotional Functioning
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 24		
n (%)	90 (69.2%)	35 (53.8%)
Mean (SD)	74.07 (20.54)	75.24 (22.91)
Median	75.00	75.00
Q1, Q3	66.67, 91.67	66.67, 91.67
Min, Max	16.7, 100.0	0.0, 100.0
Change from Baseline		
n (%)	89 (68.5%)	35 (53.8%)
Mean (SD)	8.52 (23.74)	4.29 (21.71)
Median	8.33	8.33
Q1, Q3	0.00, 16.67	-8.33, 16.67
Min, Max	-58.3, 100.0	-58.3, 58.3
Least Squares Mean (SE) [1]	7.05 (2.41)	5.08 (3.73)
95% CI [1]	2.28, 11.81	-2.30, 12.45
Least Squares Mean Difference (SE) [1]	1.97 (4.32)	
95% CI [1]	-6.57, 10.50	
p-value [2]	0.65	
Corrected Hedges' g (95% CI)	0.087 (-0.305, 0.478)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-emot.pdf 31AUG2023:16:00

Table 2.0903: EORTC QLQ-C30 Change From Baseline - Emotional Functioning
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	88 (67.7%)	35 (53.8%)
Mean (SD)	29.25 (73.62)	10.05 (42.23)
Median	11.11	9.09
Q1, Q3	-4.55, 33.33	-11.11, 25.00
Min, Max	-77.8, 300.0	-100.0, 175.0
Return Rate (%)	69%	54%
Number of Subjects in Risk	101	39
Return Rate in Risk (%)	89%	90%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-emot.pdf 31AUG2023:16:00

Table 2.0801: Cancer-Related Fatigue (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
EORTC QLQ-C30 Fatigue		
Baseline		
n (%)	129 (99.2%)	65 (100.0%)
Mean (SD)	63.82 (24.07)	55.38 (24.81)
Median	66.67	55.56
Q1, Q3	44.44, 77.78	33.33, 77.78
Min, Max	11.1, 100.0	11.1, 100.0
Return Rate (%)	99%	100%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	99%	100%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-fatigue.pdf 31AUG2023:16:00

Table 2.0801: Cancer-Related Fatigue (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 12		
n (%)	105 (80.8%)	46 (70.8%)
Mean (SD)	51.01 (25.77)	48.31 (23.68)
Median	44.44	44.44
Q1, Q3	33.33, 66.67	33.33, 66.67
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline		
n (%)	104 (80.0%)	46 (70.8%)
Mean (SD)	-12.50 (23.62)	-1.45 (17.78)
Median	-11.11	0.00
Q1, Q3	-27.78, 0.00	-11.11, 11.11
Min, Max	-77.8, 66.7	-55.6, 44.4
Least Squares Mean (SE) [1]	-12.55 (2.22)	-2.39 (3.32)
95% CI [1]	-16.93, -8.17	-8.96, 4.18
Least Squares Mean Difference (SE) [1]	-10.17 (3.88)	
95% CI [1]	-17.83, -2.50	
p-value [2]	0.010	
Corrected Hedges' g (95% CI)	-0.448 (-0.798, -0.097)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.0801: Cancer-Related Fatigue (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	104 (80.0%)	46 (70.8%)
Mean (SD)	-13.27 (48.44)	1.26 (49.65)
Median	-18.33	0.00
Q1, Q3	-35.42, 0.00	-25.00, 16.67
Min, Max	-100.0, 200.0	-100.0, 200.0
Return Rate (%)	81%	71%
Number of Subjects in Risk	121	52
Return Rate in Risk (%)	87%	88%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-fatigue.pdf 31AUG2023:16:00

Table 2.0801: Cancer-Related Fatigue (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 24		
n (%)	90 (69.2%)	35 (53.8%)
Mean (SD)	49.01 (25.09)	48.57 (22.72)
Median	50.00	44.44
Q1, Q3	33.33, 66.67	33.33, 66.67
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline		
n (%)	89 (68.5%)	35 (53.8%)
Mean (SD)	-14.23 (24.39)	-3.81 (17.03)
Median	-11.11	0.00
Q1, Q3	-33.33, 0.00	-22.22, 11.11
Min, Max	-88.9, 44.4	-33.3, 33.3
Least Squares Mean (SE) [1]	-14.34 (2.35)	-3.52 (3.65)
95% CI [1]	-18.98, -9.69	-10.74, 3.70
Least Squares Mean Difference (SE) [1]	-10.82 (4.21)	
95% CI [1]	-19.15, -2.48	
p-value [2]	0.011	
Corrected Hedges' g (95% CI)	-0.488 (-0.884, -0.093)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.0801: Cancer-Related Fatigue (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	89 (68.5%)	35 (53.8%)
Mean (SD)	-17.05 (44.89)	-4.68 (38.18)
Median	-25.00	0.00
Q1, Q3	-44.44, 0.00	-28.57, 12.50
Min, Max	-100.0, 150.0	-100.0, 100.0
Return Rate (%)	69%	54%
Number of Subjects in Risk	101	39
Return Rate in Risk (%)	89%	90%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-fatigue.pdf 31AUG2023:16:00

Table 2.0809: Cancer-Related Financial Difficulties (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
EORTC QLQ-C30 Financial Difficulties		
Baseline		
n (%)	129 (99.2%)	65 (100.0%)
Mean (SD)	13.95 (23.09)	9.74 (20.18)
Median	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
Min, Max	0.0, 100.0	0.0, 66.7
Return Rate (%)	99%	100%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	99%	100%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-finan.pdf 31AUG2023:16:00

Table 2.0809: Cancer-Related Financial Difficulties (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 12		
n (%)	105 (80.8%)	46 (70.8%)
Mean (SD)	10.48 (19.23)	10.87 (26.34)
Median	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
Min, Max	0.0, 66.7	0.0, 100.0
Change from Baseline		
n (%)	104 (80.0%)	46 (70.8%)
Mean (SD)	-4.17 (23.08)	3.62 (21.35)
Median	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
Min, Max	-100.0, 66.7	-33.3, 66.7
Least Squares Mean (SE) [1]	-3.82 (2.28)	3.99 (3.42)
95% CI [1]	-8.32, 0.68	-2.76, 10.74
Least Squares Mean Difference (SE) [1]	-7.81 (4.00)	
95% CI [1]	-15.71, 0.09	
p-value [2]	0.053	
Corrected Hedges' g (95% CI)	-0.335 (-0.684, 0.014)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.0809: Cancer-Related Financial Difficulties (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	96 (73.8%)	41 (63.1%)
Mean (SD)	-14.58 (37.64)	-7.32 (39.62)
Median	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
Min, Max	-100.0, 100.0	-100.0, 100.0
Return Rate (%)	81%	71%
Number of Subjects in Risk	121	52
Return Rate in Risk (%)	87%	88%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-finan.pdf 31AUG2023:16:00

Table 2.0809: Cancer-Related Financial Difficulties (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 24		
n (%)	90 (69.2%)	35 (53.8%)
Mean (SD)	13.33 (21.08)	9.52 (22.25)
Median	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
Min, Max	0.0, 66.7	0.0, 100.0
Change from Baseline		
n (%)	89 (68.5%)	35 (53.8%)
Mean (SD)	-1.87 (21.53)	0.00 (16.17)
Median	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
Min, Max	-66.7, 66.7	-33.3, 33.3
Least Squares Mean (SE) [1]	-1.59 (2.15)	1.40 (3.33)
95% CI [1]	-5.84, 2.65	-5.18, 7.98
Least Squares Mean Difference (SE) [1]	-2.99 (3.82)	
95% CI [1]	-10.55, 4.57	
p-value [2]	0.44	
Corrected Hedges' g (95% CI)	-0.148 (-0.540, 0.243)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.0809: Cancer-Related Financial Difficulties (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	78 (60.0%)	32 (49.2%)
Mean (SD)	-17.09 (40.02)	-10.94 (35.32)
Median	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
Min, Max	-100.0, 100.0	-100.0, 50.0
Return Rate (%)	69%	54%
Number of Subjects in Risk	101	39
Return Rate in Risk (%)	89%	90%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-finan.pdf 31AUG2023:16:00

Table 2.0906: EORTC QLQ-C30 Change From Baseline - Global Health Status/QoL
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
EORTC QLQ-C30 Global Health Status/QoL		
Baseline		
n (%)	129 (99.2%)	65 (100.0%)
Mean (SD)	45.99 (22.37)	48.08 (18.56)
Median	50.00	50.00
Q1, Q3	33.33, 66.67	33.33, 58.33
Min, Max	0.0, 100.0	0.0, 100.0
Return Rate (%)	99%	100%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	99%	100%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-global.pdf 31AUG2023:16:00

Table 2.0906: EORTC QLQ-C30 Change From Baseline - Global Health Status/QoL
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 12		
n (%)	105 (80.8%)	46 (70.8%)
Mean (SD)	49.29 (20.22)	50.72 (21.65)
Median	50.00	50.00
Q1, Q3	33.33, 66.67	33.33, 66.67
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline		
n (%)	104 (80.0%)	46 (70.8%)
Mean (SD)	3.53 (27.50)	0.18 (25.55)
Median	0.00	0.00
Q1, Q3	-8.33, 16.67	-16.67, 8.33
Min, Max	-75.0, 75.0	-66.7, 66.7
Least Squares Mean (SE) [1]	3.06 (2.75)	0.21 (4.13)
95% CI [1]	-2.37, 8.49	-7.95, 8.36
Least Squares Mean Difference (SE) [1]	2.85 (4.81)	
95% CI [1]	-6.65, 12.36	
p-value [2]	0.55	
Corrected Hedges' g (95% CI)	0.101 (-0.246, 0.449)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.0906: EORTC QLQ-C30 Change From Baseline - Global Health Status/QoL
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	100 (76.9%)	46 (70.8%)
Mean (SD)	37.41 (144.10)	8.46 (61.34)
Median	0.00	0.00
Q1, Q3	-14.29, 33.33	-28.57, 20.00
Min, Max	-100.0, 900.0	-100.0, 200.0
Return Rate (%)	81%	71%
Number of Subjects in Risk	121	52
Return Rate in Risk (%)	87%	88%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-global.pdf 31AUG2023:16:00

Table 2.0906: EORTC QLQ-C30 Change From Baseline - Global Health Status/QoL
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 24		
n (%)	90 (69.2%)	35 (53.8%)
Mean (SD)	51.94 (19.07)	52.38 (16.86)
Median	50.00	50.00
Q1, Q3	41.67, 66.67	41.67, 66.67
Min, Max	0.0, 100.0	16.7, 83.3
Change from Baseline		
n (%)	89 (68.5%)	35 (53.8%)
Mean (SD)	6.27 (27.47)	2.62 (21.93)
Median	8.33	0.00
Q1, Q3	-8.33, 25.00	-8.33, 8.33
Min, Max	-66.7, 75.0	-50.0, 50.0
Least Squares Mean (SE) [1]	4.81 (2.73)	0.66 (4.22)
95% CI [1]	-0.59, 10.21	-7.67, 8.99
Least Squares Mean Difference (SE) [1]	4.15 (4.86)	
95% CI [1]	-5.45, 13.75	
p-value [2]	0.39	
Corrected Hedges' g (95% CI)	0.161 (-0.230, 0.553)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
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Table 2.0906: EORTC QLQ-C30 Change From Baseline - Global Health Status/QoL
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	85 (65.4%)	35 (53.8%)
Mean (SD)	43.00 (125.06)	14.07 (52.50)
Median	12.50	0.00
Q1, Q3	-20.00, 50.00	-25.00, 25.00
Min, Max	-100.0, 700.0	-75.0, 150.0
Return Rate (%)	69%	54%
Number of Subjects in Risk	101	39
Return Rate in Risk (%)	89%	90%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-global.pdf 31AUG2023:16:00

Table 2.0805: Cancer-Related Insomnia (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
EORTC QLQ-C30 Insomnia		
Baseline		
n (%)	129 (99.2%)	65 (100.0%)
Mean (SD)	44.19 (34.15)	37.44 (30.91)
Median	33.33	33.33
Q1, Q3	0.00, 66.67	0.00, 66.67
Min, Max	0.0, 100.0	0.0, 100.0
Return Rate (%)	99%	100%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	99%	100%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.0805: Cancer-Related Insomnia (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 12		
n (%)	105 (80.8%)	46 (70.8%)
Mean (SD)	32.70 (30.31)	30.43 (32.07)
Median	33.33	33.33
Q1, Q3	0.00, 66.67	0.00, 33.33
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline		
n (%)	104 (80.0%)	46 (70.8%)
Mean (SD)	-10.90 (34.27)	-3.62 (32.38)
Median	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
Min, Max	-100.0, 66.7	-100.0, 66.7
Least Squares Mean (SE) [1]	-11.29 (3.43)	-4.00 (5.15)
95% CI [1]	-18.07, -4.52	-14.17, 6.17
Least Squares Mean Difference (SE) [1]	-7.29 (5.99)	
95% CI [1]	-19.12, 4.54	
p-value [2]	0.23	
Corrected Hedges' g (95% CI)	-0.208 (-0.555, 0.140)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-insom.pdf 31AUG2023:16:00

Table 2.0805: Cancer-Related Insomnia (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	94 (72.3%)	41 (63.1%)
Mean (SD)	-24.11 (57.61)	-17.89 (59.79)
Median	-33.33	0.00
Q1, Q3	-50.00, 0.00	-50.00, 0.00
Min, Max	-100.0, 200.0	-100.0, 200.0
Return Rate (%)	81%	71%
Number of Subjects in Risk	121	52
Return Rate in Risk (%)	87%	88%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-insom.pdf 31AUG2023:16:00

Table 2.0805: Cancer-Related Insomnia (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 24		
n (%)	90 (69.2%)	34 (52.3%)
Mean (SD)	31.11 (30.31)	36.27 (32.17)
Median	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline		
n (%)	89 (68.5%)	34 (52.3%)
Mean (SD)	-14.61 (36.57)	1.96 (33.78)
Median	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 33.33
Min, Max	-100.0, 66.7	-66.7, 100.0
Least Squares Mean (SE) [1]	-13.81 (3.80)	2.65 (5.92)
95% CI [1]	-21.32, -6.31	-9.06, 14.36
Least Squares Mean Difference (SE) [1]	-16.46 (6.84)	
95% CI [1]	-29.98, -2.94	
p-value [2]	0.017	
Corrected Hedges' g (95% CI)	-0.461 (-0.861, -0.062)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-insom.pdf 31AUG2023:16:00

Table 2.0805: Cancer-Related Insomnia (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	80 (61.5%)	29 (44.6%)
Mean (SD)	-28.33 (65.14)	-7.47 (61.33)
Median	-33.33	0.00
Q1, Q3	-100.00, 0.00	-50.00, 0.00
Min, Max	-100.0, 200.0	-100.0, 100.0
Return Rate (%)	69%	52%
Number of Subjects in Risk	101	39
Return Rate in Risk (%)	89%	87%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-insom.pdf 31AUG2023:16:00

Table 2.0802: Cancer-Related Nausea and Vomiting (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
EORTC QLQ-C30 Nausea and Vomiting		
Baseline		
n (%)	129 (99.2%)	65 (100.0%)
Mean (SD)	11.63 (15.95)	9.23 (16.15)
Median	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 16.67
Min, Max	0.0, 83.3	0.0, 66.7
Return Rate (%)	99%	100%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	99%	100%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.0802: Cancer-Related Nausea and Vomiting (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 12		
n (%)	105 (80.8%)	46 (70.8%)
Mean (SD)	10.32 (16.08)	3.62 (8.54)
Median	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 0.00
Min, Max	0.0, 66.7	0.0, 33.3
Change from Baseline		
n (%)	104 (80.0%)	46 (70.8%)
Mean (SD)	-1.12 (17.57)	-3.99 (14.57)
Median	0.00	0.00
Q1, Q3	-16.67, 0.00	0.00, 0.00
Min, Max	-66.7, 50.0	-50.0, 33.3
Least Squares Mean (SE) [1]	-1.09 (1.67)	-4.42 (2.50)
95% CI [1]	-4.38, 2.20	-9.36, 0.52
Least Squares Mean Difference (SE) [1]	3.33 (2.92)	
95% CI [1]	-2.43, 9.09	
p-value [2]	0.26	
Corrected Hedges' g (95% CI)	0.195 (-0.153, 0.543)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-naus.pdf 31AUG2023:16:00

Table 2.0802: Cancer-Related Nausea and Vomiting (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	94 (72.3%)	43 (66.2%)
Mean (SD)	-5.89 (77.66)	-16.67 (36.19)
Median	0.00	0.00
Q1, Q3	-50.00, 0.00	0.00, 0.00
Min, Max	-100.0, 300.0	-100.0, 0.0
Return Rate (%)	81%	71%
Number of Subjects in Risk	121	52
Return Rate in Risk (%)	87%	88%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-naus.pdf 31AUG2023:16:00

Table 2.0802: Cancer-Related Nausea and Vomiting (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 24		
n (%)	90 (69.2%)	35 (53.8%)
Mean (SD)	8.52 (16.05)	2.86 (8.56)
Median	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 0.00
Min, Max	0.0, 100.0	0.0, 33.3
Change from Baseline		
n (%)	89 (68.5%)	35 (53.8%)
Mean (SD)	-3.56 (17.85)	-7.14 (15.28)
Median	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
Min, Max	-83.3, 66.7	-50.0, 33.3
Least Squares Mean (SE) [1]	-3.12 (1.82)	-6.14 (2.83)
95% CI [1]	-6.71, 0.48	-11.73, -0.55
Least Squares Mean Difference (SE) [1]	3.02 (3.27)	
95% CI [1]	-3.44, 9.48	
p-value [2]	0.36	
Corrected Hedges' g (95% CI)	0.176 (-0.215, 0.568)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-naus.pdf 31AUG2023:16:00

Table 2.0802: Cancer-Related Nausea and Vomiting (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	83 (63.8%)	34 (52.3%)
Mean (SD)	-18.27 (68.01)	-28.43 (43.33)
Median	0.00	0.00
Q1, Q3	-100.00, 0.00	-66.67, 0.00
Min, Max	-100.0, 300.0	-100.0, 0.0
Return Rate (%)	69%	54%
Number of Subjects in Risk	101	39
Return Rate in Risk (%)	89%	90%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-naus.pdf 31AUG2023:16:00

Table 2.0803: Cancer-Related Pain (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
EORTC QLQ-C30 Pain		
Baseline		
n (%)	129 (99.2%)	65 (100.0%)
Mean (SD)	40.83 (29.83)	32.56 (25.59)
Median	33.33	33.33
Q1, Q3	16.67, 66.67	16.67, 50.00
Min, Max	0.0, 100.0	0.0, 100.0
Return Rate (%)	99%	100%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	99%	100%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.0803: Cancer-Related Pain (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 12		
n (%)	105 (80.8%)	46 (70.8%)
Mean (SD)	31.11 (27.74)	31.88 (29.57)
Median	33.33	16.67
Q1, Q3	0.00, 50.00	16.67, 50.00
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline		
n (%)	104 (80.0%)	46 (70.8%)
Mean (SD)	-10.10 (29.32)	0.72 (21.93)
Median	-16.67	0.00
Q1, Q3	-33.33, 0.00	-16.67, 16.67
Min, Max	-83.3, 66.7	-66.7, 33.3
Least Squares Mean (SE) [1]	-8.91 (2.70)	1.69 (4.05)
95% CI [1]	-14.24, -3.57	-6.31, 9.69
Least Squares Mean Difference (SE) [1]	-10.59 (4.71)	
95% CI [1]	-19.91, -1.28	
p-value [2]	0.026	
Corrected Hedges' g (95% CI)	-0.383 (-0.733, -0.034)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-pain.pdf 31AUG2023:16:00

Table 2.0803: Cancer-Related Pain (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	94 (72.3%)	44 (67.7%)
Mean (SD)	-25.35 (62.13)	3.41 (70.49)
Median	-33.33	0.00
Q1, Q3	-66.67, 0.00	-37.50, 29.17
Min, Max	-100.0, 200.0	-100.0, 200.0
Return Rate (%)	81%	71%
Number of Subjects in Risk	121	52
Return Rate in Risk (%)	87%	88%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-pain.pdf 31AUG2023:16:00

Table 2.0803: Cancer-Related Pain (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 24		
n (%)	90 (69.2%)	35 (53.8%)
Mean (SD)	27.96 (26.06)	32.86 (27.56)
Median	16.67	33.33
Q1, Q3	0.00, 50.00	16.67, 50.00
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline		
n (%)	89 (68.5%)	35 (53.8%)
Mean (SD)	-14.23 (32.23)	0.00 (22.14)
Median	-16.67	0.00
Q1, Q3	-33.33, 0.00	-16.67, 16.67
Min, Max	-100.0, 50.0	-50.0, 50.0
Least Squares Mean (SE) [1]	-11.47 (3.04)	1.03 (4.72)
95% CI [1]	-17.48, -5.46	-8.30, 10.37
Least Squares Mean Difference (SE) [1]	-12.51 (5.46)	
95% CI [1]	-23.31, -1.70	
p-value [2]	0.024	
Corrected Hedges' g (95% CI)	-0.436 (-0.831, -0.042)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-pain.pdf 31AUG2023:16:00

Table 2.0803: Cancer-Related Pain (EORTC QLQ-C30) Change From Baseline Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	81 (62.3%)	33 (50.8%)
Mean (SD)	-28.89 (70.95)	2.93 (72.28)
Median	-40.00	0.00
Q1, Q3	-100.00, 0.00	-33.33, 33.33
Min, Max	-100.0, 300.0	-100.0, 200.0
Return Rate (%)	69%	54%
Number of Subjects in Risk	101	39
Return Rate in Risk (%)	89%	90%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-pain.pdf 31AUG2023:16:00

Table 2.0901: EORTC QLQ-C30 Change From Baseline - Physical Functioning
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
EORTC QLQ-C30 Physical Functioning		
Baseline		
n (%)	129 (99.2%)	65 (100.0%)
Mean (SD)	52.89 (20.38)	56.13 (22.72)
Median	53.33	60.00
Q1, Q3	40.00, 66.67	40.00, 73.33
Min, Max	0.0, 93.3	0.0, 100.0
Return Rate (%)	99%	100%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	99%	100%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-phys.pdf 31AUG2023:16:00

Table 2.0901: EORTC QLQ-C30 Change From Baseline - Physical Functioning
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 12		
n (%)	105 (80.8%)	46 (70.8%)
Mean (SD)	59.62 (23.94)	67.17 (21.43)
Median	60.00	73.33
Q1, Q3	40.00, 80.00	53.33, 86.67
Min, Max	0.0, 100.0	13.3, 100.0
Change from Baseline		
n (%)	104 (80.0%)	46 (70.8%)
Mean (SD)	6.71 (19.62)	6.85 (16.32)
Median	6.67	6.67
Q1, Q3	-6.67, 18.33	-6.67, 20.00
Min, Max	-51.7, 66.7	-26.7, 40.0
Least Squares Mean (SE) [1]	6.53 (1.88)	6.78 (2.82)
95% CI [1]	2.81, 10.25	1.20, 12.36
Least Squares Mean Difference (SE) [1]	-0.25 (3.30)	
95% CI [1]	-6.77, 6.27	
p-value [2]	0.94	
Corrected Hedges' g (95% CI)	-0.013 (-0.360, 0.334)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.0901: EORTC QLQ-C30 Change From Baseline - Physical Functioning
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	104 (80.0%)	46 (70.8%)
Mean (SD)	24.99 (77.22)	20.13 (52.04)
Median	11.81	9.17
Q1, Q3	-14.29, 37.50	-7.69, 36.36
Min, Max	-100.0, 500.0	-60.0, 220.0
Return Rate (%)	81%	71%
Number of Subjects in Risk	121	52
Return Rate in Risk (%)	87%	88%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-phys.pdf 31AUG2023:16:00

Table 2.0901: EORTC QLQ-C30 Change From Baseline - Physical Functioning
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 24		
n (%)	90 (69.2%)	35 (53.8%)
Mean (SD)	61.63 (22.11)	65.43 (23.32)
Median	60.00	73.33
Q1, Q3	46.67, 80.00	46.67, 83.33
Min, Max	13.3, 100.0	0.0, 100.0
Change from Baseline		
n (%)	89 (68.5%)	35 (53.8%)
Mean (SD)	8.28 (17.78)	6.33 (15.69)
Median	6.67	0.00
Q1, Q3	0.00, 13.33	-6.67, 20.00
Min, Max	-33.3, 80.0	-28.3, 46.7
Least Squares Mean (SE) [1]	7.68 (1.88)	5.08 (2.93)
95% CI [1]	3.95, 11.41	-0.72, 10.87
Least Squares Mean Difference (SE) [1]	2.60 (3.37)	
95% CI [1]	-4.07, 9.28	
p-value [2]	0.44	
Corrected Hedges' g (95% CI)	0.147 (-0.245, 0.538)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-phys.pdf 31AUG2023:16:00

Table 2.0901: EORTC QLQ-C30 Change From Baseline - Physical Functioning
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	89 (68.5%)	35 (53.8%)
Mean (SD)	29.67 (82.27)	15.93 (49.63)
Median	11.11	0.00
Q1, Q3	0.00, 37.50	-7.69, 30.00
Min, Max	-62.5, 600.0	-100.0, 180.0
Return Rate (%)	69%	54%
Number of Subjects in Risk	101	39
Return Rate in Risk (%)	89%	90%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-phys.pdf 31AUG2023:16:00

Table 2.0902: EORTC QLQ-C30 Change From Baseline - Role Functioning
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
EORTC QLQ-C30 Role Functioning		
Baseline		
n (%)	129 (99.2%)	65 (100.0%)
Mean (SD)	55.56 (29.85)	59.23 (28.11)
Median	66.67	66.67
Q1, Q3	33.33, 83.33	33.33, 83.33
Min, Max	0.0, 100.0	0.0, 100.0
Return Rate (%)	99%	100%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	99%	100%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-role.pdf 31AUG2023:16:00

Table 2.0902: EORTC QLQ-C30 Change From Baseline - Role Functioning
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 12		
n (%)	105 (80.8%)	46 (70.8%)
Mean (SD)	61.59 (29.61)	68.84 (28.02)
Median	66.67	66.67
Q1, Q3	50.00, 83.33	50.00, 83.33
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline		
n (%)	104 (80.0%)	46 (70.8%)
Mean (SD)	4.81 (30.25)	2.90 (27.06)
Median	0.00	0.00
Q1, Q3	-16.67, 33.33	0.00, 16.67
Min, Max	-66.7, 100.0	-66.7, 66.7
Least Squares Mean (SE) [1]	5.06 (2.94)	4.10 (4.41)
95% CI [1]	-0.76, 10.87	-4.62, 12.82
Least Squares Mean Difference (SE) [1]	0.95 (5.14)	
95% CI [1]	-9.20, 11.11	
p-value [2]	0.85	
Corrected Hedges' g (95% CI)	0.032 (-0.315, 0.379)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.0902: EORTC QLQ-C30 Change From Baseline - Role Functioning
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	97 (74.6%)	46 (70.8%)
Mean (SD)	16.13 (85.55)	17.03 (73.61)
Median	0.00	0.00
Q1, Q3	-20.00, 33.33	0.00, 33.33
Min, Max	-100.0, 500.0	-100.0, 400.0
Return Rate (%)	81%	71%
Number of Subjects in Risk	121	52
Return Rate in Risk (%)	87%	88%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-role.pdf 31AUG2023:16:00

Table 2.0902: EORTC QLQ-C30 Change From Baseline - Role Functioning
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 24		
n (%)	90 (69.2%)	35 (53.8%)
Mean (SD)	62.59 (29.49)	61.43 (26.74)
Median	66.67	66.67
Q1, Q3	33.33, 83.33	50.00, 66.67
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline		
n (%)	89 (68.5%)	35 (53.8%)
Mean (SD)	5.99 (32.30)	-2.86 (25.72)
Median	0.00	0.00
Q1, Q3	-16.67, 16.67	-16.67, 16.67
Min, Max	-66.7, 100.0	-66.7, 33.3
Least Squares Mean (SE) [1]	4.18 (3.28)	-5.45 (5.09)
95% CI [1]	-2.30, 10.66	-15.51, 4.62
Least Squares Mean Difference (SE) [1]	9.63 (5.89)	
95% CI [1]	-2.02, 21.27	
p-value [2]	0.10	
Corrected Hedges' g (95% CI)	0.312 (-0.081, 0.705)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.0902: EORTC QLQ-C30 Change From Baseline - Role Functioning
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	84 (64.6%)	35 (53.8%)
Mean (SD)	23.25 (90.51)	4.52 (57.69)
Median	0.00	0.00
Q1, Q3	-25.00, 33.33	-33.33, 25.00
Min, Max	-100.0, 500.0	-100.0, 200.0
Return Rate (%)	69%	54%
Number of Subjects in Risk	101	39
Return Rate in Risk (%)	89%	90%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-role.pdf 31AUG2023:16:00

Table 2.0905: EORTC QLQ-C30 Change From Baseline - Social Functioning
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
EORTC QLQ-C30 Social Functioning		
Baseline		
n (%)	129 (99.2%)	65 (100.0%)
Mean (SD)	67.31 (29.05)	72.56 (27.86)
Median	66.67	83.33
Q1, Q3	50.00, 83.33	66.67, 100.00
Min, Max	0.0, 100.0	0.0, 100.0
Return Rate (%)	99%	100%
Number of Subjects in Risk	130	65
Return Rate in Risk (%)	99%	100%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Data Extracted: CRF data: 13JAN2022
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-eortc-chg-gba.sas V.03.05 Output file: t-eortc-chg-social.pdf 31AUG2023:16:00

Table 2.0905: EORTC QLQ-C30 Change From Baseline - Social Functioning
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 12		
n (%)	105 (80.8%)	46 (70.8%)
Mean (SD)	74.76 (27.84)	78.99 (26.40)
Median	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline		
n (%)	104 (80.0%)	46 (70.8%)
Mean (SD)	7.69 (30.72)	0.00 (27.89)
Median	0.00	0.00
Q1, Q3	-16.67, 25.00	0.00, 16.67
Min, Max	-66.7, 100.0	-100.0, 50.0
Least Squares Mean (SE) [1]	8.64 (2.99)	1.65 (4.48)
95% CI [1]	2.74, 14.54	-7.20, 10.50
Least Squares Mean Difference (SE) [1]	6.99 (5.23)	
95% CI [1]	-3.36, 17.33	
p-value [2]	0.18	
Corrected Hedges' g (95% CI)	0.228 (-0.120, 0.576)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.0905: EORTC QLQ-C30 Change From Baseline - Social Functioning
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	100 (76.9%)	46 (70.8%)
Mean (SD)	25.22 (81.67)	6.78 (42.60)
Median	0.00	0.00
Q1, Q3	-18.33, 41.67	0.00, 20.00
Min, Max	-100.0, 500.0	-100.0, 150.0
Return Rate (%)	81%	71%
Number of Subjects in Risk	121	52
Return Rate in Risk (%)	87%	88%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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Table 2.0905: EORTC QLQ-C30 Change From Baseline - Social Functioning
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Week 24		
n (%)	90 (69.2%)	35 (53.8%)
Mean (SD)	76.48 (22.61)	75.71 (25.03)
Median	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline		
n (%)	89 (68.5%)	35 (53.8%)
Mean (SD)	8.99 (28.87)	-1.90 (23.84)
Median	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 16.67
Min, Max	-66.7, 83.3	-100.0, 33.3
Least Squares Mean (SE) [1]	8.93 (2.94)	-0.02 (4.56)
95% CI [1]	3.11, 14.75	-9.03, 9.00
Least Squares Mean Difference (SE) [1]	8.95 (5.25)	
95% CI [1]	-1.43, 19.32	
p-value [2]	0.091	
Corrected Hedges' g (95% CI)	0.323 (-0.070, 0.716)	

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

Table 2.0905: EORTC QLQ-C30 Change From Baseline - Social Functioning
Over the 24-Week Randomized Treatment Period
Intent-To-Treat (ITT) Analysis Set

	MMB (N=130)	DAN (N=65)
Percent Change from Baseline		
n (%)	85 (65.4%)	35 (53.8%)
Mean (SD)	29.69 (83.13)	0.43 (27.96)
Median	0.00	0.00
Q1, Q3	0.00, 50.00	0.00, 20.00
Min, Max	-75.0, 500.0	-100.0, 50.0
Return Rate (%)	69%	54%
Number of Subjects in Risk	101	39
Return Rate in Risk (%)	89%	90%

[1] Least squares mean (SE), least squares mean difference (SE), and confidence intervals (95%) are from mixed model for repeated measures (MMRM) including terms for treatment arm, timepoint (week), treatment-by-week interaction, MFSAF TSS baseline score (<22, >=22), baseline palpable spleen length below the left costal margin (<12cm, >=12cm), and baseline RBC units transfused in the 8-week period prior to Randomization (0, 1-4, 5+).
[2] p-value for the least squares mean difference between the two arms from the MMRM.

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