14.2.2 Secondary endpoints

14.2.2.5 Change in constitutional symptoms

Table 14.2.2.5.1: Change in weight from before Ruxolitinib induction therapy (baseline) to after 3 months from start of Ruxolitinib induction therapy - Safety Population

Treatment arm	Visit	N	Mean (SD)	Median	Min, Max	Mean of differences (95% CI)	T-statistic	P-value
ContRuxo	Baseline	16	78.9 (14.8)	79.0	56.0 , 110.0	2.443 (1.605 - 3.281)	5.81	<0.001
	After 3 months of induction	16	81.8 (14.5)	85.0	57.5 , 110.0			
SCT	Baseline	58	82.5 (12.5)	81.3	60.0 , 116.0			
	After 3 months of induction	58	84.8 (13.4)	84.5	62.0 , 117.0			

ContRuxo: Ruxolitinib continuous therapy. SCT: Allogeneic stem cell transplantation.
Method: two-sided paired t-test assuming equal variances. Columns three to six show descriptive statistics for the treatment arms at the specified timepoints while columns seven to nine show parameters from the paired t-test for the comparison between treatment arms

Table 14.2.2.5.2A: Change in number of sweats per night from before Ruxolitinib induction therapy (baseline) to after 3 months from start of Ruxolitinib induction therapy - Safety Population

Treatment arm	Visit	N	Wilcoxon test statistic	P-value
ContRuxo	After 3 months of induction	14	382.5	0.008
	Baseline	14		
SCT	After 3 months of induction	49		
	Baseline	49		

ContRuxo: Ruxolitinib continuous therapy. SCT: Allogeneic stem cell transplantation.
Method: two-sided Wilcoxon signed rank test with continuity correction. Due to presence of zeros and ties in the rank differences, no exact p-values computed. Shown p-value based on the normal approximation.
Column three shows sample size used in the analysis per the treatment arm for the specified timepoints while columns four and five show parameters from Wilcoxon signed-rank test for the comparison between treatment arms

Table 14.2.2.5.2B: Descriptive statistics of number of sweats per night by visit and treatment arm - Safety Population

Treatment arm	Visit	Number of night sweats	N (%)
ContRuxo	Baseline	0	1 (7.1)%
		1	3 (21.4)%
		2	2 (14.3)%
		3	2 (14.3)%
		4	1 (7.1)%
		7	2 (14.3)%
		8	1 (7.1)%
		9	1 (7.1)%
		10	1 (7.1)%

ContRuxo: Ruxolitinib continuous therapy. SCT: Allogeneic stem cell transplantation. All percentage values are rounded to 1 decimal place. Only records used in the analysis for comparison of change in number of sweats per night before Ruxolitinib induction therapy (baseline) to after 3 months from start of Ruxolitinib induction therapy between treatment arms are shown. Total N for Safety Population used in analysis (complete data for both visits) in SCT arm = 49 and ContRuxo arm= 14

Table 14.2.2.5.2B: Descriptive statistics of number of sweats per night by visit and treatment arm - Safety Population

Treatment arm	Visit	Number of night sweats	N (%)
ContRuxo	After 3 months of induction	0	4 (28.6)%
		1	5 (35.7)%
		3	1 (7.1)%
		6	2 (14.3)%
		7	1 (7.1)%
		9	1 (7.1)%

ContRuxo: Ruxolitinib continuous therapy. SCT: Allogeneic stem cell transplantation. All percentage values are rounded to 1 decimal place. Only records used in the analysis for comparison of change in number of sweats per night before Ruxolitinib induction therapy (baseline) to after 3 months from start of Ruxolitinib induction therapy between treatment arms are shown. Total N for Safety Population used in analysis (complete data for both visits) in SCT arm = 49 and ContRuxo arm= 14

Table 14.2.2.5.2B: Descriptive statistics of number of sweats per night by visit and treatment arm - Safety Population

Treatment arm	Visit	Number of night sweats	N (%)
SCT	Baseline	0	8 (16.3)%
		1	6 (12.2)%
		2	11 (22.4)%
		3	6 (12.2)%
		4	7 (14.3)%
		5	4 (8.2)%

ContRuxo: Ruxolitinib continuous therapy. SCT: Allogeneic stem cell transplantation. All percentage values are rounded to 1 decimal place. Only records used in the analysis for comparison of change in number of sweats per night before Ruxolitinib induction therapy (baseline) to after 3 months from start of Ruxolitinib induction therapy between treatment arms are shown. Total N for Safety Population used in analysis (complete data for both visits) in SCT arm = 49 and ContRuxo arm= 14

Table 14.2.2.5.2B: Descriptive statistics of number of sweats per night by visit and treatment arm - Safety Population

Treatment arm	Visit	Number of night sweats	N (%)
SCT	Baseline	6	2 (4.1)%
		7	2 (4.1)%
		8	1 (2.0)%
		9	1 (2.0)%
		10	1 (2.0)%

ContRuxo: Ruxolitinib continuous therapy. SCT: Allogeneic stem cell transplantation. All percentage values are rounded to 1 decimal place. Only records used in the analysis for comparison of change in number of sweats per night before Ruxolitinib induction therapy (baseline) to after 3 months from start of Ruxolitinib induction therapy between treatment arms are shown. Total N for Safety Population used in analysis (complete data for both visits) in SCT arm = 49 and ContRuxo arm= 14

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Table 14.2.2.5.2B: Descriptive statistics of number of sweats per night by visit and treatment arm - Safety Population

Treatment arm	Visit	Number of night sweats	N (%)
SCT	After 3 months of induction	0	12 (24.5)%
		1	14 (28.6)%
		2	7 (14.3)%
		3	7 (14.3)%
		4	2 (4.1)%
		5	3 (6.1)%
		6	1 (2.0)%
		8	1 (2.0)%
		9	2 (4.1)%

ContRuxo: Ruxolitinib continuous therapy. SCT: Allogeneic stem cell transplantation. All percentage values are rounded to 1 decimal place. Only records used in the analysis for comparison of change in number of sweats per night before Ruxolitinib induction therapy (baseline) to after 3 months from start of Ruxolitinib induction therapy between treatment arms are shown. Total N for Safety Population used in analysis (complete data for both visits) in SCT arm = 49 and ContRuxo arm= 14

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