14.2.2 Secondary endpoints

Table 14.2.2.6A: Change in grading of bone marrow fibrosis 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	8	83	0.623
	Baseline	8		
SCT	After 3 months of induction	37		
	Baseline	37		

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 14.2.2.6B: Descriptive statistics of grading of bone marrow fibrosis by visit and treatment arm - Safety Population

Treatment arm	Visit	Bone marrow fibrosis grading	N (%)
ContRuxo	Baseline	MF-1	1 (12.5)%
		MF-2	4 (50.0)%
		MF-3	3 (37.5)%
	After 3 months of induction	MF-1	1 (12.5)%
		MF-2	3 (37.5)%
		MF-3	4 (50.0)%

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 grading of bone marrow fibrosis 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 = 37 and ContRuxo arm= 8

Table 14.2.2.6B: Descriptive statistics of grading of bone marrow fibrosis by visit and treatment arm - Safety Population

Treatment arm	Visit	Bone marrow fibrosis grading	N (%)
SCT	Baseline	MF-1	1 (2.7)%
		MF-2	13 (35.1)%
		MF-3	23 (62.2)%
	After 3 months of induction	MF-1	3 (8.1)%
		MF-2	13 (35.1)%
		MF-3	21 (56.8)%

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 grading of bone marrow fibrosis 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 = 37 and ContRuxo arm= 8

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