

14.2 Efficacy Analysis

14.2.1 Primary endpoint

Table 14.2.1.1: Chronic GvHD and progression-free survival (cGRFS) from SCT (Kaplan-Meier) - Full Analysis Population

Time to event from SCT [days]	Survival Function Estimate	Standard Error	95% Lower confidence interval	95% Upper confidence interval
28	0.972	0.027	0.920	1.000
54	0.944	0.038	0.873	1.000
58	0.917	0.046	0.831	1.000
87	0.889	0.052	0.792	0.998
104	0.861	0.058	0.755	0.982
141	0.833	0.062	0.720	0.964
146	0.806	0.066	0.686	0.946
161	0.778	0.069	0.653	0.926
172	0.750	0.072	0.621	0.906

GvHD: Graft-versus-Host Disease. All numerical values are rounded to 3 decimal places. Standard error calculated using Greenwood's formula.
Reference- Cantor AB. Projecting the standard error of the Kaplan-Meier estimator. Stat Med. 2001 Jul 30;20(14):2091-7. doi: 10.1002/sim.856. PMID: 11439423.

Page 1 of 3

Table 14.2.1.1: Chronic GvHD and progression-free survival (cGRFS) from SCT (Kaplan-Meier) - Full Analysis Population

Time to event from SCT [days]	Survival Function Estimate	Standard Error	95% Lower confidence interval	95% Upper confidence interval
174	0.722	0.075	0.590	0.884
230	0.694	0.077	0.559	0.862
301	0.667	0.079	0.529	0.840
442	0.639	0.080	0.500	0.817
449	0.611	0.081	0.471	0.793
470	0.583	0.082	0.443	0.769
494	0.556	0.083	0.415	0.744
547	0.528	0.083	0.387	0.719
564	0.500	0.083	0.361	0.693

GvHD: Graft-versus-Host Disease. All numerical values are rounded to 3 decimal places. Standard error calculated using Greenwood's formula.
Reference- Cantor AB. Projecting the standard error of the Kaplan-Meier estimator. Stat Med. 2001 Jul 30;20(14):2091-7. doi: 10.1002/sim.856. PMID: 11439423.

Page 2 of 3

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Time to event from SCT [days]	Survival Function Estimate	Standard Error	95% Lower confidence interval	95% Upper confidence interval
577	0.472	0.083	0.334	0.667
587	0.444	0.083	0.308	0.640
630	0.417	0.082	0.283	0.613
639	0.389	0.081	0.258	0.586

GvHD: Graft-versus-Host Disease. All numerical values are rounded to 3 decimal places. Standard error calculated using Greenwood's formula.
Reference- Cantor AB. Projecting the standard error of the Kaplan-Meier estimator. Stat Med. 2001 Jul 30;20(14):2091-7. doi: 10.1002/sim.856. PMID: 11439423.

Page 3 of 3

Figure 14.2.1.1: Chronic GvHD and progression-free survival (cGRFS) from SCT (Kaplan-Meier) - Full Analysis Population

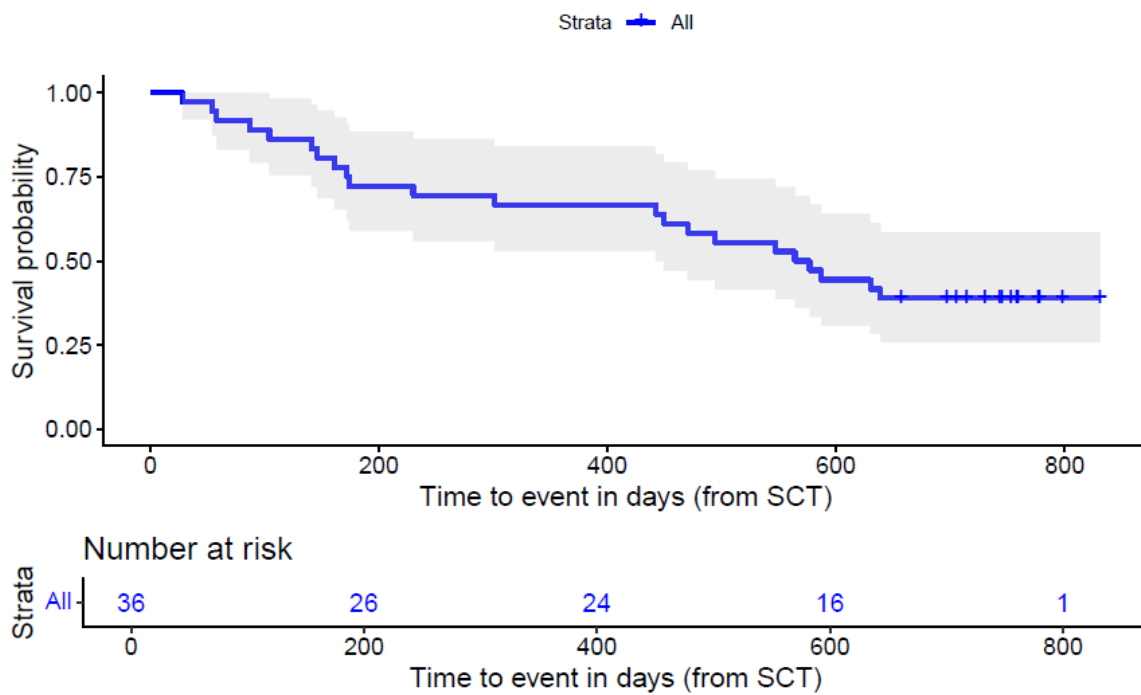


Table 14.2.1.2: Comparison of cGRFS at 2 years after SCT between patients with multiple myeloma and historical reference data - Full Analysis Population

Time from SCT	Survival Function Estimate	Standard Error	95% Lower confidence interval	95% Upper confidence interval	Z-value	P-value
2 years	0.389	0.081	0.258	0.586	2.940	0.003
GvHD: Graft-versus-Host Disease. All numerical values are rounded to 3 decimal places. Standard error calculated using Greenwood's formula. Reference- Cantor AB. Projecting the standard error of the Kaplan-Meier estimator. Stat Med. 2001 Jul 30;20(14):2091-7. doi: 10.1002/sim.856. PMID: 11439423.						
Page 1 of 1						

Table 14.2.1.3: Chronic GvHD and progression-free survival (cGRFS) from start of salvage therapy (Kaplan-Meier) - Full Analysis Population

Time from start of salvage therapy	Survival Function Estimate	Standard Error	95% Lower confidence interval	95% Upper confidence interval
1 year	0.846	0.071	0.718	0.997
2 years	0.615	0.095	0.454	0.834
GvHD: Graft-versus-Host Disease. All numerical values are rounded to 3 decimal places. Standard error calculated using Greenwood's formula. Reference- Cantor AB. Projecting the standard error of the Kaplan-Meier estimator. Stat Med. 2001 Jul 30;20(14):2091-7. doi: 10.1002/sim.856. PMID: 11439423.				
Page 1 of 1				

Figure 14.2.1.3: Chronic GvHD and progression-free survival (cGRFS) from start of salvage therapy (Kaplan-Meier) - Full Analysis Population

